# EXHIBIT 2F

WAVE 1

# EXHIBIT

# F

SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY/CIVIL DIVISION
DOCKET NO. ATL-L-6966-10

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LINDA GROSS and JEFFREY GROSS, Plaintiffs, : STENOGRAPHIC TRANSCRIPT OF:

v. : - TRIAL -

GYNECARE, ETHICON, INC., JOHNSON & JOHNSON, and JOHN DOES 1-20, Defendants.

- - -

PLACE: ATLANTIC COUNTY COURTHOUSE
1201 Bacharach Boulevard
Atlantic City, New Jersey

DATE: February 4, 2013

- - -

B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

- - -

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E X A M I N A T I O N S

- - -

THE COURT: You can be seated.
Ready to start? Bring the jury in.
- - -
(The jury enters the courtroom.)
- - -
THE COURT: You can be seated.
Your next witness, Mr. Slater.
MR. ANDERSON: Yes, Your Honor. Plaintiffs call Dr. Uwe Klinge.
- - -
PROF. DR. UWE KLINGE, after having been duly sworn, was examined and testified as follows:
- - -
THE CLERK: Would you state your full name, spell your last name for the record.
THE WITNESS: My name is Klinge, Uwe.
THE COURT: You can be seated.
- - -
VOIR DIRE - DIRECT EXAMINATION
- - -
BY MR. ANDERSON:
Q Good morning, Dr. Klinge.
A Good morning.
Q Can you please tell the jury where you live?



A I'm living in Montzen. That is a small village at the eastern part of Belgium. And this is about 10 miles away from Aachen. This area is very close to the Netherlands, Germany, Belgium, where all these countries are coming together, and I'm living in this place.
Q And did you come here from Belgium to testify in front of this jury here today?
A That is correct.
Q Dr. Klinge, please tell the jury your profession?
A With the help of my CV, I started medical school in --
Q First of all -- I'm sorry.
First of all, tell them your profession.
Are you an abdomen surgeon?
A I'm an abdominal surgeon and a biomaterial researcher, including histology, pathology, with the focus of meshes in soft tissue -- in soft tissues, yeah.
Q Before we get into the issues in this case involving Prolift, tell the jury a little bit about your background and your training and your education, please.
A Okay. I started medical school in 1977 at the



Technical University in Aachen and finished it in 1983, in the shortest time. Their Technical University is one of the most famous centers in Germany, and one of the main topics of it is engineering. And it is one of the biggest institutes, for example, for textile engineering as well, which later on was a big advantage for me.
So after passing medical school, I went to -- or I started residency at the surgical department at the University Hospital in Aachen. This hospital is one of the biggest buildings in size in Europe. And it is a major hospital in this area, attracting a lot of patients from Belgium and the Netherlands as well. I started residency there and learned the basic principles of surgery, passed several hundreds of operations. And after having done all this, usually -- or you pass or I passed an examine, at some official office there. And afterwards, I got -- I became a specialist for general surgery. That was in 1993.
Afterwards, I became oberartz, that is a function that is quite similar to being an attendant surgeon on call. That means that you're fully responsible for what your residents are doing there and you're responsible for a certain number of patients.
Q Dr. Klinge, if I could just stop you there.



You said that Aachen University was a leading textile and surgical implant facility.
Where does Aachen University rank in terms of surgical mesh research facilities in the entire world?
A In the moment, because of our work, the -- we are at the top of this -- in this field.
Q And who is the top surgical mesh biomaterial science researcher at this top facility in the world?
A I would have to say me.
Q You talked about becoming a specialist for general surgery in 1993, and then you went up to 1999 in terms of getting your oberartz, which allowed you to be an attending.
My question is, during this time as you became a surgeon, did you begin to perform hernia surgeries?
A Yes. Indeed, it is a necessary part for becoming a specialist of general surgery to perform about 100 of hernia operations there. And, therefore, I had to do a lot of hernia surgeries in the time period after becoming a specialist. And after becoming a specialist in the beginning of the '90s, there are an increasing number of operations used meshes. So, therefore, in

this time period of the beginning of the '90s, we increasingly get aware of meshes to be used as reinforcement of the tissues.

Q In the abdominal wall?

A In the abdominal wall.

Q Okay. Sorry for interrupting you. Let's go back to, I think you were up to 2000?

A So this was the career as a surgeon. And in parallel, there is an academic career in Germany. And it started to make a first scientific work, usually you start during the medical school. And this was done by me in the department for biochemistry where I had a -- had to look at the red blood cells, whether they are able to attract oxygen and to deliver this in the tissue. So I made some -- about for three years, I worked in this department and made a thesis so that afterwards, I was allowed to take the title of doctor.

So this was the first step there. Then later in 1993, and I'm sure we will talk about later on about it, 1993 we start to work scientifically on this meshes, not least because of our experience with this -- with our patients. And then I started to work scientifically, and for the next seven years, and all this together allowed me to apply for the venia legendi. Venia legendi does mean that if you get this



permission, then you're allowed to represent surgery in lectures for the students and all over the hospital.

So I got this permission in 2000. To get this, you have to collect all your scientific work. You have to collect or to list all the publications. And then it's going to an internal board and to an external revision or reviewer. And then if they accept and said, okay, it's qualified enough, then you get this venia legendi and then you get the new title as privatdozent.

Q What does that mean?

A It sounds a little bit strange. I think, or I know that it's only available in Austria and in Germany till now, but we are used to it for 100 years. So it definitely means that you have shown that you're able to do some science successfully and that you're able to work as a professor. But it is not sufficient to be a professor. But if you get this title of privatdozent, then you have to still work on for the next five, six years. You have to collect your research project. You have to collect all this literature. You publish there. And after these five, six years, you can apply again, and then again an internal board, an external board. And then if they accept this, then you get the title of a professor.



So this is the end of the academic career in Germany. And it took -- it was the end of a long -- of a long trip of 28 years for me. So it was almost exactly after 28 years after I started to study in Aachen, then I got the title finally of the professor. And this was in -- so I have to look. It was in 2005. Yeah, in 2005.

Q In terms of the specific work that you performed and the research and the publications that you were talking about, between 1993 and 2000, in order to -- I know I'm going to mispronounce it, but the venia legendi, in order to achieve that level, was that research that you did during those seven years specifically with regard to tissue response, biomaterial science and surgical meshes for the human body?

A That is correct. And it started with our experience of hernia meshes or meshes in the abdominal wall, where we got aware that some of these patients have serious complications. They have a lot of wound liquid around these devices. Some of them have pain, some of them have infection, some of them has fistula formation to the bowels. So we have serious problems in some of these patients, and we got a little bit concerned. And we wanted to know what is the reason



for this.

If you made a revision operation of these patients and you are looking to these devices, during implantation, they are looking quite nice, very flat, very smooth, and you have a good feeling that it's now a very strong repair. But if you are looking after three months, after six months, they are completely -- it's a stiff plate, they are integrated only in scar tissue and curled up and wrinkled. And we wanted to understand what is the reason for this change from the textile to this -- what we have seen in the OR. And there are hundreds of images showing what happens to these textile products after placing in the soft tissue.

THE COURT: Counsel, we want to -- do you want to offer the witness as an expert?

MR. ANDERSON: I had a little bit more, but I'm happy to.

THE COURT: Well, it seemed to me he was going into the substance of his testimony as opposed to just qualifications at this point. So can we just stick to qualifications and then --

MR. ANDERSON: Certainly.

BY MR. ANDERSON:

Q So you were talking about the work that was

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necessary for you to achieve this habilitacion and venia legendi from 1993 to 2000.

Okay. We'll get back to some of that work. Okay?

A Yes.

Q We will come back.

A Yeah, yeah, yeah.

Q So in 2000, what did you do? Let me ask you this before we do that.

In addition to biomaterial science, tissue response for surgical meshes during this 1993 to 2000 time period where you did all of this research in order to obtain the venia legendi, did that also involve histopathological review of this tissue response?

A Yes, exactly. It is an integrative part of these investigations, to look at the soft tissues.

Q Please explain to the jury what histopathology is as it relates to our bodies -- our body's tissue response to surgical meshes like Prolift?

A So histology, histology is that you want to analyze what happens to the tissues. And usually you need a microscope to see this. Usually surgeons only at the microscopical level and they saw what they can feel and what they have in their hands. So to understand this a little bit better, you need to use a

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microscope and to look a little bit more deeper to the details. And that is histology. That is the science of the tissues.

If there are some diseases or if there is some injury and damage, then you have a pathology. And you can learn from the pathology what is the disease in the background, what is the reason for the injury. And, therefore, it is necessary to look to the histology and pathology to understand what happens in the OR with these materials. It was an essential part of this study.

Q And just in its most simplest form, during these years from '93 to 2000, in all of this research that you were doing, were you looking at the body's response to polypropylene meshes in human tissue after being implanted with surgical meshes like Prolift?

A That's correct. That is a part of it.

Q Okay. And then I see from your CV in 2000 you became the principal investigator of the surgical department at Aachen University.

Just briefly explain that to the jury, if you would?

A The other research projects dealing with the meshes, and I'm the leader of all these projects, they have an amount of money and work there that it has to

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be coordinated a little bit better. And we build up or we increase the resources in our lab. And I was put in charge to organize all this and to be responsible for this work.

I just would like to point out, maybe in the next time I sometimes mixed up I and we, I was told that it is -- may be a little bit different here.

In science, it is only fair to say "we," because the work is done by a team, and so, therefore, I very often will say "we." But, in fact, I'm responsible for everything there, so if you want to charge me, it is an I. So maybe -- yeah. So that you have it correct, even if I say "we," it's...

Q Fair enough. Thank you.

And then in 2002 you became the specialist for surgical intensive care medicine at Aachen University surgical department; is that correct?

A That is correct. We have a -- yeah. We have an own intensive care unit for -- in our surgical department at that time, and I was working there for several years. And I have to pass an examine for this and then I qualified as a specialist for intensive care, surgical intensive care medicine as well.

Q And then from 2003 to 2006, you were assistant medical director of the entire facility.

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Can you please explain that?

A There has been two assistant medical directors or vice chairmen in our department, and I was one of it. So if the other two are not in the hospital, you are responsible for everything. So everyone will know what does it mean.

Q So in 2004, you became a specialist in abdominal surgery. Briefly explain that to the jury.

A So a specialist in general surgery means that you are -- that you know the standard operations and that you can -- you're able to do them in full responsibility. This visceral surgery, the specialist for this means that you are able to perform advanced surgical procedures. That means extended oncologic resections, bowel resections, resections of the esophagus or something like that and liver resection.

So you have to do another number of, but now major operations, and then you have to pass an examine and then you're allowed to do these operations in full responsibility. And then you get the specialist for visceral surgery. I don't know whether it's here.

Q Is visceral surgery another way of saying abdominal surgery?

A Yes.

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Q And from 2006 to 2009, I see that you had a cooperation with the Helmholtz Institute.

Just briefly explain, please, what work you did for those three years with biomedical engineering in cooperation with the surgical department, biomaterial science and engineering.

A The main focus of the entire university, but as well of the hospital, is the focus of medical engineering. And, therefore, one part of the University Hospital is this Helmholtz Institute. It includes five, six different institutes. 90 percent of the employees are engineers. So it is the bridging between engineering and medicine. And I had the opportunity to work there for three years.

Q After that, did you return to Aachen University as the principal scientific investigator?

A It sounds a little bit difficult, but it's only 200 meters or 250 yards, I think. So I returned back to the surgical department, because it was more easy to coordinate this research activities then.

Q Were you the principal scientist supervising these research activities in biomaterial science research for surgical meshes to be implanted in bodies, like the Gynemesh PS Prolift in this case?

A It didn't change since 2000.

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Q So that's true?

A And it's still there, yeah.

Q Now I'd like to talk a little bit about your work between 1995 and 2005.

In addition to being an abdominal surgeon with all the specialties that you have described and all the different certifications that you have received and being a principal biomaterial science investigator in the surgical department looking at tissue engineering and histopathology, in addition to those things, now I'd like to talk about any work that you may have done with outside medical device manufacturers. Okay?

A Yes.

Q Can you please explain to the jury this consulting work that you did with outside medical device manufacturers using your expertise from 1995 to 2005?

A So as I've said, in 1993 we've got the problem with these implants, and, therefore, we established a comprehensive work on these materials for, first of all, to define some requirements and then to study them, what happens there. And if you want to study the effects of these materials, you need to have a lot of various materials to define the impact. And, therefore, it was very, very helpful to have someone who provides you with the material, with the suture material, so that you can then test the impact of all the different properties to the tissue. And this has been Ethicon. And it started in 1994, where we, in a close collaboration, studied the impact of various material modifications on the soft issue.

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Q And when you say "we," is that in collaboration between you and your group in Aachen and Ethicon in Norderstedt?

A Yes, yes. It is a large group. It is several different institutes within the hospital of Aachen. It is five, six people from the R&D department of Ethicon Norderstedt. And it's been about ten surgical colleagues which are all integrated into this field.

Q How extensive was the work that was done during that decade, from 1995 to 2005, between you and Ethicon?

A It was a very close collaboration, so we have a lot of phone calls, because, in the beginning, we wanted to define. We had to make a -- we had to define the requirements for this material, and then we made a lot of tests, about 20 different materials. And so we permanently exchanged the results. There were working meetings at least four times a year. We have the

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entire group from Norderstedt came to Aachen, and where a whole day we have been discussing what we have done, the results and what has to be done in future.

Q When you began this consulting relationship with Ethicon, was this the first time that the scientific community had begun to look at the tissue response in humans to surgical meshes?

A It was not the first time. There are some single investigations in the '80s. But it was the first time that you want to create a comprehensive scientific support for a medical device and to make a specific design for a specific use. That was the first time.

MR. GAGE: Your Honor, just wondering if we're still on voir dire or if we're kind of getting more into the substance.

MR. ANDERSON: I'm just trying to get through his credentials.

THE COURT: Okay. Then just stay away from what his investigations discovered and just outline his career, that's fine.

BY MR. ANDERSON:

Q Explain what you have done over the last 20 years in terms of -- strike that.

We heard a little bit about your biomaterial science research and your looking into the

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tissue response of surgical meshes like Prolift to the human body. And you mentioned histopathology.

Tell the jury a little bit about your training in histopathology over these 20 years, just briefly.

A The analysis of histopathology to foreign body materials, it's not a very simple question, even if I -- I'm asked to do it briefly. Because what we started to do to look to the soft tissues in 1994, I went to the department for pathology, and there was no one who could help us who could say that we knew how to quantify or qualify the histological implants or the cellular response to these materials. And they sent me away.

And, fortunately, there has been a colleague who made his residence in surgery there before, so I know him. And he's a pathologist, Dr. Klosterhalfen. I think he's well known for everyone who is in this business. And he said, okay, I don't know it either, but let's try. And, therefore, in this year, in 1994, we started to establish the principles how to analyze the soft tissue reaction. And he knows a lot of different markers, and we together tested all these markers, whether they are helpful to differentiate between the good materials and the best

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materials. And that was established there, and you will find it in the publications, in the early publications, they focus on this principles how to make this analysis.

And in the following years, we used this knowledge, we improved permanently, we looked at -- I looked at thousands of these stainings --

Q By stainings do you mean --

A Sections, histological sections. Where you look at tissue --

Q Slides from tissue pathology?

A Yes.

Q Okay.

A Where you have the soft tissue and the biomaterial and where you have to define what is the extent of inflammation and fibrosis there.

Q Can I stop you right there?

You mentioned fibrosis. So was part of what you were doing was looking at the body's responses to meshes that may cause fibrosis or scarring? Is that true?

A Yeah.

Q Shrinkage of the mesh once it's in the tissue?

A Yes.

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Q And the complications that result due to fibrosis, shrinking in the human body?

A Yes.

Q So this work in terms of biomaterial science, the tissue response and the histopathology and your experience as an abdominal surgeon who had implanted meshes, was this all being put together so that you could analyze the problems that were happening with patients with meshes?

A This was our big advantage to combine all these three experiences. And you cannot separate this.

Q Great. Have you published -- let me go back.

The jury has heard what peer-reviewed literature means, so I don't want to go back through that, but have you published in the peer-reviewed literature?

A Yes.

Q How many publications do you have in the peer-reviewed literature?

A You will find about -- more than 200 publications, and I hope the number will increase.

Q And how many of those relate directly to surgical meshes either for the abdominal wall or the pelvic floor?

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A More than 100 of it.

Q How many times have those publications been cited as references by other authors in the scientific community?

A Last time I looked, it was more than 2,000.

Q So your work on surgical meshes in the literature has been cited by other scientists over 2,000 times; is that correct?

A It's highly recognized, yeah.

Q Have you written books and published book chapters?

A Several book chapters.

Q How many?

A 50, about 50.

Q How many of those 50 related to the issues in this case, surgery involving mesh, biomaterials science and tissue response?

A 45.

Q 45 books and book chapters?

A Book chapters.

Q Yes.

Have you been an invited lecturer to conferences?

A Yes.

Q Approximately how many times -- I see in

your CV that you've lectured over 200 times and 130 times as oral presentation as an invited lecturer.

So of those 330 times that you've given lectures, approximately what percentage of those were relating to the issues in this case, surgical mesh, biomaterials and tissue response and the problems that can happen in a human being as a result of those?

A It's about 90 percent or more.

Q 90 percent of the 330 times you've been asked to speak?

A Yes.

Q Have you been asked to speak by Ethicon at conferences?

A Yes.

Q How many times?

A Some dozens.

Q Dozens of times.

And do you continue to be an invited speaker for Ethicon at conferences?

A Yes.

Q When was the last time you were invited by Ethicon to speak at a conference for them?

A It was in the week of my deposition. So two days later on I was asked to give a presentation for Ethicon in Brussels, and the weekend I was asked to do a



presentation in Munich for Ethicon, to present the history of meshes, because in some regards, I represent 20 years of history of meshes.

Q Have you been invited to lecture to your peers on pelvic floor meshes like Prolift?

A Yes.

Q How many times?

A About 10 to 15 times.

Q And the audience at these conferences where you've been asked to lecture on pelvic floor meshes, have there been gynecologists at the conferences?

A Yes.

Q Urologists at other conferences?

A Yes.

Q Urogynecologists at other conferences?

A Yes.

Q In fact, have you been asked by Ethicon to speak to urogynecologists at their Norderstedt facility regarding pelvic floor repair meshes and how they can create problems in the human body?

A Yes.

Q Have you been a peer reviewer for scientific journals?

A Yes.

Q Approximately how many different journals



per year are you a peer reviewer where you are looking at your peers' submitted literature?

A It's varying a little bit between five and ten different journals per year.

Q And how many different manuscripts do you review per year, in other words, publications that have been submitted, in order to determine whether or not they should be allowed to be published in the scientific literature?

A It's around 25 to 35 a year.

Q Do they relate to the fields of surgery, biomaterials science, tissue reaction, histopathology and wound healing?

A Most of it, yeah.

Q Have you received a number of grants over the years?

A Yes.

Q The jury may have heard about NIH grants. We're talking about grants for you in Germany.

What is a grant, just briefly?

A If you want to make a research project, it usually costs money. And you need some resources, personal resources consumers, and so you have to apply to get the money. And usually this is reviewed. And if it's accepted, then you get the resources and then



you can start to work for it. And, therefore, a big time or -- yeah. We spend a lot of time to apply for these grants to get the money for our research. And in Germany, it is the Ministry, it's the German Society for Research where you can go to a hospital, and we successfully got several grants, too, for our research.

Q Approximately how many grants have you received over the years?

A About 20.

Q So approximately 20 times someone has deemed your work to be important enough to fund it?

A Yes.

Q And how many of those have involved surgical mesh, biomaterials science, tissue response and histopathology of meshes like Prolift to be permanently implanted in a woman's body?

A All except two.

Q Do you hold any patents?

A Yes.

Q How many patents do you hold?

A Seven.

Q Do they all relate to surgical mesh?

A Yes.

Q Have you served as an independent court-appointed expert in Germany?

A Yes.
Q On approximately how many occasions?
A It's about three dozen, four dozen.
Q So if you are -- three or four dozen, so somewhere around maybe 30 or 40 times a court has appointed you in Germany as an independent expert to come in and give your opinions?
A Yes.
Q You talked a lot about your hernia surgery, your abdominal surgery and all the other things you've done. You aren't coming here today as a pelvic floor surgeon, are you? I'm sorry. I asked the double negative.
You don't perform pelvic floor surgery. Correct?
A That is correct, yeah.
Q You're not coming in here as a urogynecologist. Right?
A I'm an abdominal surgeon.
Q You are not a urologist. Right?
A No. That is right, I'm not.
Q I will try to do better. We will try to do better.
You are not -- you are not a gynecologist. Correct?



A It is correct that I'm not.
Q So what is it about your background, training, experience that you believe gives you an expertise to talk to the jury today about a surgical mesh like Prolift that actually is implanted by urogynecologists?
A We have made extensive research, over 20 years, to look what happens if you use meshes in the soft tissue, what has to be considerate to get an optimum device. That is the focus of all our research in this field. And there is hardly anyone else who can -- who has this experience of -- as we have.
Q By "we," do you mean you?
A Yes.
Q And I understand you're a humble person and you're trying to give the "we" credit to others, but I need to ask you now, because the jury is hearing from you today, to put it simply, is there anyone else in the world who has studied over the last 20 years and published more articles, anyone who has done more work than you in the area of surgical meshes for -- that would be used for the abdominal wall or the pelvic floor and done more research or studied the biomaterials science, the histopathology and the surgical implications for surgical meshes in the human body?



A There is none.
MR. ANDERSON: At this time, plaintiffs would offer Dr. Uwe Klinge as an expert in the fields of abdominal surgery, biomaterial science, tissue reaction and tissue engineering, histopathology for surgical meshes in the human body.
MR. GAGE: Your Honor, we'll reserve cross.
THE COURT: Okay. The Court finds that the witness is qualified to give his opinions to the jury as an expert in those fields. You can proceed.
MR. ANDERSON: Thank you, Your Honor.
- - -
DIRECT EXAMINATION
- - -
BY MR. ANDERSON:
Q Did I approach you back in 2011 and ask you to be an expert in this case?
A Yes.
Q Did I agree to pay you for your time?
A Yes.
Q Did I ask you to review an enormous amount of materials and ultimately write an expert report in this case?
A Surely.



Q Let's talk about the materials that I, over the course of that year-and-a-half, have sent to you and that you've reviewed.
You've looked at over 500 Ethicon internal documents. Correct?
A At least.
Q Representing hundreds if not a few thousand pages?
A Yes.
Q Over 100 to 150 pieces of literature?
A That is correct.
Q Depositions of at least 30 witnesses, some of them covering multiple days?
A Yes.
Q Numerous expert reports?
A Yes.
Q Have you looked at somewhere between 15 and 20,000 pages of documents?
A Yes.
Q Did I agree to pay you $100 an hour for travel and $500 an hour for the work that you've done?
A That is correct.
Q And you've spent over 200 hours in the past year-and-a-half helping me work on this case?
A That is correct.

Q For all of the review that we just mentioned, all of those documents and then writing a 68-page report; is that right? Something like that?
A Yes.
Q Dozens of references in that report, preparing for and sitting for a two-day deposition, coming here and preparing for trial and then speaking here at trial today, have I paid you somewhere around $100,000 for that work?
A That is correct.
Q Do you believe that when you work for someone that you should be compensated?
A That is fair.
MR. ANDERSON: Your Honor, before I begin with the next portion, I was wondering if it would be okay if I have the bailiff pass the -- allow the mesh to be passed around to the jury.
THE COURT: Sure. If there's no objection from counsel.
MR. GAGE: What is it?
MR. ANDERSON: The product, the Prolift.
THE COURT: Show Mr. Gage what you're going to do, just in case he does have an objection.
BY MR. ANDERSON:
Q Since we're going to be talking about the



biomaterial science and specifically we're going to spend the rest of our time talking about Gynemesh PS and Prolift for the jury. Okay? So I just wanted to give them an opportunity to pass this amongst yourselves quickly, as long as you need to take, but then we'll move along with your questioning. Okay?
A That's fine.
THE COURT: One of the jurors wants a break, so as soon as we're done passing the mesh, we'll take a short break.
MR. ANDERSON: Yes.
THE COURT: You will have this in the jury room with you when you deliberate. You'll also have stacks of evidence that have been admitted, so you will have a lot of documents and other things with you in the jury room at the end of the case. I just want you to know that.
Okay. We can take the jury out for a minute.
- - -
(The jury leaves the courtroom.)
- - -
THE COURT: Take a break.
- - -
(A recess was taken from 10:05 a.m.



to 10:35 a.m.)
- - -
THE COURT: Let's argue this motion about tomorrow quickly.
It's the expert argument for tomorrow?
MR. MAZIE: For Hinoul?
MS. JONES: I don't know which one you're talking about.
THE COURT: You filed a motion on Piet Hinoul. Right?
MR. MAZIE: Right.
THE COURT: To prevent him from referring to any research or articles. It seems to go even further and suggests he can't refer to any manuals or brochures, but you're not trying to suggest he can't discuss the label or the patient brochure. Right?
MR. MAZIE: No. It's really the literature, Your Honor. He's not an expert. He wasn't even in the company back in 2004, 2005 and 2006. He didn't join until 2008. And, in fact, apparently he didn't come to the United States until --
THE COURT: Well, it may not even be an issue. Ms. Jones may not be intending to take him through the medical literature. I don't know if you know yet, or if you want to wait --



MS. JONES: Your Honor, he was the corporate designee on this issue and has been asked a number of questions already, as Your Honor may recall, about what happened, you know, before he got there.
I don't intend to go through the literature with him as I would with an expert. Part of his job responsibilities, though, have been evaluating the risks and benefit of the product. And he is certainly familiar with, and has written as part of his responsibilities, reports analyzing the risk and the benefits and looking at the various studies that are out there. I think since he did that in the course of his day-to-day work and responsibility, that he's entitled to testify about that and to the extent that it's included within those reports that he's got.
MR. MAZIE: Judge --
THE COURT: I don't think the objection is to his testifying about risks and benefits or any report that he wrote. I think it's just to putting a learned treatise up on the --
MR. MAZIE: It goes further than that, Judge. He's a fact witness. Just because he's designated for our purposes to give us information at a deposition, we're now at trial. And at trial, he's either a fact witness as to what he actually did, and

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he wasn't there. I mean, he didn't even come until over two years after it's implanted in Linda Gross. So he's certainly not an expert. He hasn't been designated as an expert. So we can put that aside.

He can talk about what he did in 2004, 2005 and 2006, but he didn't do anything.

THE COURT: Well, you know, I always have this two-way street thing going on. The bottom line is you put in a lot of evidence of things that occurred in 2008, 2009, 2010, and Mr. Slater argued repeatedly that the Ethicon people had admitted that everything that they knew in -- that everything that came out in 2009 they knew in 2005.

So, I mean, it's like when your witnesses are on the stand, they're saying you shouldn't be putting on post-surgical events, information. When they're on the stand, now you want to say they shouldn't be putting on post?

MR. MAZIE: They can do it, but not with this witness is my point. My point is, he's a fact witness. If they want to bring somebody in from 2005 to say this is what we looked at, this is how I drafted this, they can do that. It's not for this witness is our point. He's not an expert. He's a guy that came later on after all these -- everything that happened in

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this case happened. And they certainly are more than welcome to bring in anybody that was involved in those decisions. I don't have a problem with that. I mean, I thought we made that clear in the brief.

It's that Dr. Hinoul is not an expert and he was not there, so he's not a fact witness. He can't testify to facts that happened then because he's a fact witness. That's the point. He can certainly go into things back and forth, but the fact that he's now analyzed it in 2009 or 2010, I don't know how that affects what was done back in 2005.

MS. JONES: First of all, what he has done in the course of his day-to-day responsibilities now is done as a fact witness. In terms of other aspects of this, Your Honor, he's already been cross-examined by -- on a significant number of things that relate to pre-2006. Certainly we are entitled to have him explain his answers and go through that. And the plaintiffs chose to go with him.

MR. SLATER: Judge, we don't object obviously to the extent I asked Mr. Hinoul questions, obviously he can be asked by counsel about what I asked him. And I kept it very narrow. I did not ask him one question about the IFU. I didn't ask him any questions about the brochures or the warnings or anything about

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that. Zero. And our position is he wasn't -- with regard to warnings and things like that, he shouldn't be talking about what was done in '04 or '05, because that's factual testimony beyond the scope of what he was asked when we put him on the witness stand within the scope of his corporate designation, which is for our purposes.

If he wants to talk about warnings that were provided in '08, '09 and 2010, I mean, I suppose he could, but then he's going to start implicating all the issues the defense doesn't bring in, because those warnings are all the warnings that -- the warnings that existed when he came to the company, that was right when they were changing all their warnings, when the public health notifications were coming out and they were reacting to that, when the FDA was telling them to change their warnings. So that factually he's at the company in the point in time when the defense doesn't want to bring that in, so -- and those warnings post-date Linda's surgery, so I wouldn't expect them to ask him any questions about warnings for those reasons.

You know, I asked him primarily questions about the design intent, which was within his designation, and the complications the company knew of, because he was designated from medical affairs to talk

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about the known complications. I mean, we've been through the transcript. That's the -- pretty much what he was asked about. There may be a question here or a question there about a few other things, but that's pretty much it.

And I studiously stayed away from many areas that I didn't want to open the door on, because I didn't think it was appropriate to give him those questions. And factually he's not at the company in that time period. So as far as the literature, the other part of the motion, obviously, is just that they have an expert, you know, presumably, who is going to talk about the literature, so --

THE COURT: Well, she's already said he's not going to talk about the literature.

MR. SLATER: Okay. I might have...

THE COURT: You have asked him about the risks and benefits, or at least the risks and the complications. They certainly are going to be able to ask him about the benefits to counter that. But this isn't within the scope of your cross. That's not the issue. The issue is -- and I realize the brief wasn't fashioned that way, but the issue is what can he testify to.

He is a corporate representative. Can she

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put him on the stand to go through the IFU? Does he have to have been there when that IFU was published for her to go through the IFU with the jury with him? I don't think so. That's not expert testimony to say this is what it said, this is what we warned about. It would be nice to have a person from 2005, but then you didn't call the person from 2005, you called him. And now they're going to call him.

MR. SLATER: We videotaped her. It was Charlotte Owens.

MR. MAZIE: We asked for her to come in.

MR. SLATER: And David Robinson, we videotaped him, too. He's not available either.

MR. MAZIE: So we have technically called them. I mean, you know, that was implicit -- the reason there's a corporate designee is for our purposes, not for theirs. It's to make -- because we need someone with the most knowledge to educate themselves, and that was discovery.

MR. SLATER: He was only designated on specific issues, and I focused on only really, you know, the design intent and the complications. I really didn't go beyond that with him, I mean, other than a few straggling questions on --

THE COURT: Well, I'm assuming that her

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focus is going to be on the design intent, the complications and the benefits.

MR. MAZIE: My only concern is how does that cross over and does it cross over into expert testimony from a guy who wasn't even there when this was happening? That's what we wanted to bring to Your Honor's attention. They're going to have Dr. Murphy tomorrow, I think. He's going to go into all of this. Then they are going to bring in someone who wasn't even at the company until two years after Linda has it implanted in her, and he's really giving the same testimony. I have no problem with him going into what he did in '08, '09, '10, '11, '12 to today. But to go back and do what Dr. Murphy is doing and to maybe go through why it's safe, because he studied on it after he came to the company, is really expert testimony. It's inappropriate.

MR. SLATER: And cumulative. I mean, we dropped witnesses. We dropped Dr. Margolis in strict adherence to Your Honor's rulings that we couldn't have two people talk about causation. So we dropped someone who would have been a very persuasive witness on that issue.

THE COURT: If his testimony is repetitive or cumulative, you can object. If the questions are

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outside the scope of his ability to testify, you can object. Let's wait and see where it goes. If she wants to put the IFU up there and go through and this is what was in and this is what your company did warn about, I'm going to let her use him for that purpose. That I don't think is improper. I think you asked him about the IFU -- well, you might not have asked him about the IFU, but you definitely have asked him, you know, things that were relative to 2005, or at least you argued that they were at the time.

MR. SLATER: On the complications, absolutely. Knowledge of complications, that's what I asked him about. I didn't ask him one question about what they warned about on purpose.

MR. MAZIE: Can I ask for clarification? With regard to the primary emphasis of the motion, which really was going through the literature --

THE COURT: Well, the primary thing was literature, which she said he's not going to do, except that to the extent that he wrote a report, he may testify as to what his report was. But he's not going to testify to this is a learned treatise from so and so and this is what the finding was and this is what the statistics from that report were and that's what they mean. That's going to be confined to her expert.

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And the primary thrust of your motion was devoted to learned treatises. And you have won on that part, won by concession, because the defense has agreed that they weren't going to use him for that.

MS. JONES: Thank you.

THE COURT: So when it comes to where he's testifying, if you think he's going beyond the bounds, then you're just going to have to object as we go along. We're just going to have to rule, but, you know, just to say to him, is this what was in effect at the time, he's a corporate rep, even though I understand what you're saying, that he should be confined to a period of time, but he can, as the designee of the company, stand here and say this was our warning in 2005.

MR. MAZIE: Okay.

THE COURT: Now, he is subject to cross about whether they changed it or not. Well, we'll deal with that bridge when we get to it.

MR. SLATER: That was my only concern, obviously.

THE COURT: But at this point, he'll be testifying as to, you know, whatever he knows. And as a corporate representative, he does know what the IFU was. He knows what an IFU is. He knows what a patient

brochure is. Can he testify that in 2005 we did this for this reason or that reason? Probably not. But he can say, this is what the known benefits were at that time, and this is what the known downsides were, based on the literature that exists within the company. I'm going to allow him to do that. All right?

MR. SLATER: We should wait and see if it's cumulative and deal with it?

THE COURT: Anything -- yeah, obviously. I don't expect him to be a duplicate of their expert in any way. I mean, there's going to be an overlap, because the jury has to hear it from a company representative as to what the company knew, too. I mean, you can't -- I think they have to have some company representative. And if, as they've represented, they can't bring in some of these other people, then -- I'm going to let them have some leeway with that. I'm just going to let you know that. They're not going to go into literature, they're not going to be cumulative, and we'll see where it goes.

MR. SLATER: Fair enough.

THE COURT: And if you feel that we're going over those boundaries, object question by question.

MR. SLATER: Thank you.



THE COURT: We'll proceed.

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(The jury enters the courtroom.)

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THE COURT: Continue with the witness.

MR. ANDERSON: Thank you, Your Honor.

BY MR. ANDERSON:

Q If you could put up slide 1, please.

Dr. Klinge, you had indicated to the jury before the break that you'd written over 100 articles that relate directly to surgical meshes in the human body. Correct?

A That is correct.

Q Clearly we're not going to go through those 100 articles or anywhere close to it, but I did want to bring to the jury's attention six of your important ones, okay?

A Yeah, that is okay.

Q In 1998, PLT0268, what was that study about in terms of mesh must adapt to the physiology? Briefly explain that to the jury.

A So that the conception of this work was to define the requirements to design a mesh and to test whether it changes the reaction of the tissues. And with the help of the people from Hamburg-Norderstedt, this was



the first result. So we were able to produce a modified mesh that is adapted to the physiological requirements. And in this study, we could show that it really improves the tissue integration.

Q And just be a little more specific if you would, please, about what you mean by, to define the physiological requirements of the mesh?

A The basic principle of this mesh was that we found out that most of the older meshes have been oversized. They are much too strong in comparison to what is needed in the abdominal wall. Therefore, we could reduce the amount of material down to 30 percent. And that means that we were able to enlarge the pore size. And this mesh has a reduced amount of work and has large pores of more than 3 millimeter.

Q When you say "this mesh," you're not talking about the Prolift mesh, you're talking about the mesh that you were studying. Correct?

A That was this new development.

Q Okay. Go ahead.

Okay. Then in 1998, you had another publication. Briefly explain to the jury what was brought to the scientific world as a result of that publication?

A One major concern of these meshes that is our



experience during the operations was the strong scar formation and the shrinkage and the folding of these meshes. So, therefore, we wanted to test whether these new meshes with the larger pores really can reduce the amount of shrinkage. And in this preclinical study, we could show that both are of polypropylene, but now we have a mesh material with lower weight, with larger pores, and in fact, the degree of the extent of shrinkage could be reduced significantly.

Q And just to be clear, when we're talking about larger pores, the jury just handled the Prolift mesh. We're talking about the holes that go throughout the mesh; is that correct?

A That is correct.

Q And then in 1999 --

THE COURT: Well, wait. Back in the 1998, it says 30 percent to 50 percent PP mesh shrinks.

Was the mesh shrinking between 30 and 50 percent or was that a reduction in the amount of shrinkage? What does that 30 to 50 percent mean?

THE WITNESS: The one mesh, the bad mesh shrank up to 50, whereas the better showed only a shrinkage of only 30 percent.

THE COURT: Go ahead.

BY MR. ANDERSON:

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Q To clarify that point -- thank you, Your Honor -- it's not actually the mesh itself shrinking, it's the scar around the mesh that's pushing it together; is that correct?
A Yes, that is absolutely correct. But in our terms and in our discussions, we, some years ago, stopped to make this differentiation, because everyone knows that polypropylene does not shrink itself. It's a wound contraction.
Q And when we talk about contracting mesh or bunching mesh or shrinking mesh, we're talking about the same thing, just different words. Correct?
A Yes.
Q Speaking of the foreign body reaction, what did you publish in 1999, Dr. Klinge?
A So our next point was that we wanted to know what happens to this reaction of the tissue to the foreign body materials after long term, whether it sometimes ended or not. And in this study of human explants, we could show that there is an ongoing inflammation at the interface between the fiber and the surrounding tissue. And it never ends. It's going to be a little bit smoother over the years, but you always have some sort of inflammation there. And it is like a chronic wound which can persist for, yeah, lifelong.

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Q And then in 2002 you published some other findings. Explain that to the jury briefly.
A The basic question was what was the reason for this scar formation? Was it some cells, was it some inflammation or -- and in this study, we could identify that the pore size, it's the outstanding critical component that defines whether you have a lot of scar formation around the mesh. And, therefore, pore size is -- mainly determines how good a mesh will be incorporated and how safe it is in the last consequence. And there we saw that if you have small pores with less than 1 millimeter in diameter, usually all this area is filled just by scar tissue, what we don't want to have.
Q And did Ethicon fund that study in 2002?
A Yes.
Q So am I correct, Dr. Klinge, that by 2002, Ethicon knew that in order to prevent mesh shrinkage and the problems associated with it, you needed to have pore sizes greater than 1 millimeter; is that correct?
A It's correct. All these findings have been extensively discussed together at our working meetings.
Q And do you have an opinion as to whether or not Ethicon knew by 2002 that pore sizes, these holes, would have fibrotic bridging, scarring across the hole,

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have a scar plate around the mesh and lead to shrinkage and complications in patients if those pores were not greater than 1 millimeter? Do you have an opinion?
A Yes.
Q And did they? Were they aware of this?
A Yes. Of course they were aware of it, because that -- one of the reasons that we -- or one of our advantages were that we published all these details so that the scientific community has free access to all these results, all manufacturers have free access of all these results. So the data came maybe one, two years before. But in the moment where this is published, everyone has free access to this information.
Q Thank you, Dr. Klinge.
And then just two more here I want to go through. 2005, lightweight, large pore concept.
What was that a publication regarding?
A All these findings together were just summarized in this article, and it was named as the lightweight, large pore concept. And the various aspects are much more -- they were summarized in this article, and this was a term, it's a concept.
Q So is it fair to say that between 1995 and 2005, you and your group in Aachen brought to the

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scientific world the idea of tissue reaction to surgical meshes and how you would measure it?
A Yes.
Q Brought to the scientific world the fact that polypropylene meshes can shrink if you don't have the proper design requirements?
A That is correct.
Q Brought to the scientific world that there is a foreign body reaction to surgical meshes and it will have a chronic inflammatory response, chronic wound, that the design of the mesh may be able to reduce?
A Absolutely.
Q And in 2002, did you, you and your colleagues, bring to the scientific world for the first time the idea that all of this work could be -- that some of these problems would be avoided if you had pore sizes that had 1 millimeter in diameter throughout the course of the mesh?
A That has been the main message of this work and many presentations following and before.
Q Was the purpose for doing this work in order to try to improve patient safety?
A Yes.
Q Was the purpose of this work to try to help

manufacturers design better meshes for the area of the body where they were going to be placed?

MR. GAGE: Objection, leading.

MR. ANDERSON: I'll withdraw it.

BY MR. ANDERSON:

Q What was the purpose of this work other than the safety in terms of the design for manufacturers to be able to have this knowledge?

A It was proven by our work that it was possible that defining the requirements, designing a better mesh, studying it, that this can improve the tissue response to these mesh materials and improve the safety of the patient. And that was later on, and in these years as well, there -- it was -- we added a lot of clinical studies to show this. It was not only preclinical work, but all this together confirmed for many, many, many times that it is an advantage. And, meanwhile, large pore meshes in Germany and in Europe, it's outstanding.

Q Okay. Doctor, I'm going to ask you about a couple of opinions. And I want to let you know that any of the opinions that you state here to the jury and before this Court today, according to New Jersey law, have to be stated to a reasonable degree of scientific or medical probability.



You don't have to use those words, just can we assume that if you're going to offer opinions, that it is stated to a reasonable degree of medical or scientific probability, unless you tell us otherwise. Fair enough?

A That is fair.

Q After your review of tens of thousands of pages of documents, deposition testimony, your 20 years of work in the field and your ten years of work with Ethicon, Dr. Klinge, do you have an opinion as to whether or not Gynemesh PS in Prolift is safe to be permanently implanted in a woman's pelvic tissue?

A Yes, I have an opinion.

Q And what is that opinion?

A It is not a safe design and it never had a chance to be.

Q To be safely implanted in a woman's pelvic tissue?

A Yes.

Q Do you have an opinion as to -- strike that.

What is the general basis of that opinion that Gynemesh PS in Prolift could never be safely implanted permanently in a woman's pelvic tissue?

A The structural disadvantage of this mesh is that



you have rather small pores that are even made smaller by some filaments crossing these pores. You have a complete collapse of pores if you placed it under mechanical strain. And this together leads to an incorporation of the entire device into scar formation. And that means by maturing of the scar shrinkage, that the entire area of the mesh gets integrated into the scar plate. And in the area of pelvic floor, this is disastrous in regard to the function of the organs to the dynamic of the structures in the pelvic floor.

Q Do you have an opinion, Dr. Klinge, as to whether or not Ethicon was aware, prior to the Prolift launch in March of 2005, of these problems?

A No doubt.

Q Dr. Klinge, you were telling the jury earlier about these years that your group in Norderstedt would have meetings and things like that with the folks at Ethicon Norderstedt.

Do you recall that?

A Yes, yes.

Q At any of the meetings prior to the launch of Prolift in March 2005, were there discussions about Ethicon's idea of putting mesh into a woman's pelvic floor?

A We never have been involved in the development of



the Prolift, but it was -- I had a discussion with Brigitte Hellhammer who --

Q Hold on.

Brigitte Hellhammer?

A Brigitte Hellhammer.

Q Was she an Ethicon employee from Norderstedt?

A She was an employee and working at the R&D department in Norderstedt, and she was part of this group that regularly came to Aachen to discuss all these results. And in 2000, she told me that there is --

MR. GAGE: Objection.

MR. ANDERSON: Admission.

MR. GAGE: May we approach?

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(The following occurred at sidebar:)

MR. GAGE: Your Honor, I object to the witness on the basis of hearsay of providing an out of court statement. And I wouldn't normally approach just for that, but I figure this is a good to time to approach on a bigger issue.

This is an expert witness who has been designated solely as an expert witness. His interactions with Ethicon obviously formed part of the

basis of his expertise and it's just historical fact of what his job function is. So for that reason, I thought it was appropriate not to object and let the witness get into this. But it appears that where we're headed now is a factual historical recitation by the expert of what Ethicon -- of his personal interactions with Ethicon as to what they knew and when they knew it. And as an expert witness and solely designated as such and not designated as a fact witness, I would object to the witness going in that direction.

MR. ANDERSON: It's an admission by Ethicon as to the fact that they were going to put these meshes in the pelvic floor. He was their consultant at the time. He was their expert consultant at the time. He talked about all of the work that he did with them in terms of trying to improve the design of various things, and what he's about to tell this Court and this jury, if Your Honor will allow it, is that when they told him that they were going to do that, he said then you better use all these principles that we've been working on for the last many years if you're going to put it in the pelvic floor. Then we're going into the e-mail showing that they didn't listen to him.

THE COURT: I'm going to allow the fact testimony as well as the expert testimony. He had



factual interactions with them. I can't -- certainly someone can testify as both a fact witness and an expert witness. And I can't believe that -- well, it's not that I can't believe it, but I think it's obvious from the beginning that he's been called both as an expert and because he previously had been a consultant for Ethicon. That's been mentioned several times.

I'm going to allow it. This is an admission. It's not hearsay. And your objection is overruled but preserved for the record.

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(The sidebar ended.)

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BY MR. ANDERSON:

Q Let's reorient ourselves to where we were.

I had asked you if in any of your meetings as a consultant for Ethicon whether or not the idea that Ethicon was thinking about using surgical meshes in the pelvic floor was brought to your attention at one of these meetings.

Do you remember where we were in our testimony?

A Yes, yes.

Q Okay. And you were telling the jury about that meeting that you had with Brigitte Hellhammer?



A Yes.

Q Please start over or continue in that.

A Certainly. In 2000, she told me that it was planned to use meshes for the reinforcement of the pelvic floor. And I told her that, in this case, they should adopt the principles that we developed the years before to define the requirements, to make a design and to focus on large pore mesh constructions, that they should use these principles to avoid damage by other structures.

Q And when you're talking about requirements, you told her about that it needs to adapt to the physiology of the area where they're going to place it?

A Yeah. But it has to be defined for the pelvic floor. We did it just for the abdominal wall, but it has to be defined for.

Q So the work that you had done with Ethicon up at that point, you had defined the requirements for the abdominal wall. Is that what you're saying?

A Yes.

Q But it had not been defined for the pelvic floor for putting mesh down there. Correct?

A Yes, correct. But it should have been done, yes.

Q Did you explain to her that it would be unsafe to do that if you hadn't defined these



requirements?

A Yes.

Q Out of all of the depositions and the documents reviewed, could you tell whether or not she actually followed your advice? Did they in fact follow your advice? Did they use these principles when they designed Prolift?

A Obviously they did not, because the Gynemesh PS or the Prolift does not show these structural requirements. What we found out was essential.

Q In order to be -- you mean essential in order to be permanently implanted in a woman's pelvic tissue?

A Yes. And to be safe and to not make this scar tissue response.

Q If we could look at the next slide, please, Uri.

And this is --

Dr. Klinge, you have seen these e-mails; is that correct?

A That is correct.

Q I believe the jury has seen these as well.

July -- June of 2003, an e-mail from Michel Cosson to Scott Ciarrocca.

Who is Michel Cosson?

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A He's one of the inventor or promoter of the Prolift.
Q From your review, you understand Scott Ciarrocca was the Ethicon R&D team member that was the head of the Prolift project?
A That is correct.
Q E-mail, "The problems are more erosion, retraction. It is possible to have a recurrence, but it is usually due to a retraction of the mesh and the arms of the mesh are still left in place in those cases."
And then the second e-mail, the e-mail from Ophelie Berthier to Zenobia Walji, May 10, 2004, you've seen that as well. Correct?
A Yes.
Q And in that e-mail, it says, "I know you're working on the new mesh materials with Gene and I'd like to share with you the inputs of Prof. Jacquetin and Dr. Cosson."
And you know that Prof. Jacquetin is who?
A He's the other inventor of this procedure.
Q "Their main concern is now the shrinkage of the mesh, which may lead to pain, dyspareunia...indeed now they have tremendously improved the technique, lowered the erosion rate, what needs to be improved is

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the shrinkage of the mesh (in this case, Gynemesh Soft)."
Do you see that?
A I see it, yeah.
Q These e-mails in 2003 and 2004, are they significant to your opinions in this case?
A Yes. But the contents of these meshes -- messages is not really surprising, because they just form out what was the fear what will happen. So at that time point, yeah, they should stop and study it.
Q Stop the project, study the problems?
A Yes. Would be most appropriate.
Q Did they do that?
A No.
Q If we could see the next slide, please.
Before we do that, if we could go back.
These e-mails, you said your meeting with Brigitte Hellhammer was in 2000. Correct?
A Yes.
Q Then the e-mail on the left is 2003. Correct?
A Yes.
Q And then this one is 2004?
A Yes.
Q So this one is two years before the Prolift

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is launched?
A That is correct.
Q Indicating these problems?
A Yes.
Q And this is a year before Prolift was launched indicating these problems. Correct?
A That is correct.
Q You were still a consultant with Ethicon in 2003-2004. Correct?
A That is correct.
Q After this meeting in which you warned Brigitte Hellhammer about the problems if they didn't use the right design for something that was going to go into a woman's pelvis, did they come to you and say, we have got problems with erosion and retraction, can you please help us on this, Dr. Klinge?
A I was never contacted in this field.
Q When an e-mail comes from the people who invented the TVM technique a year before the launch indicating shrinkage, pain, dyspareunia, what needs to be improved is shrinkage, did they come to someone who had published on shrinkage and ask him to help them?
MR. GAGE: Objection.
BY MR. ANDERSON:
Q You?

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MR. GAGE: No way the witness can know that.
THE WITNESS: That it --
MR. ANDERSON: Let me ask the witness.
BY MR. ANDERSON:
Q Did they come to you and ask you that?
MR. GAGE: Your Honor, that wasn't the question. The question was, did they go to anyone.
THE COURT: He's rephrasing whether they came to him.
MR. ANDERSON: Yes, ma'am. Sorry.
BY MR. ANDERSON:
Q Did anyone come to you when they became aware of these problems with Gynemesh PS in the Prolift a year before the launch?
A No, they didn't come.
Q Had they come to you, would you have been willing to use the work that you'd been putting in for five years to try to help them avoid these problems?
A Of course.
Q Show the next document, please.
You reviewed this document as well, Dr. Klinge?
A Yes.
Q The jury has seen this. This is an Ethicon

expert meeting in 2006.

What's your understanding as to why Ethicon was having this meeting with inside consultants and outside consultants in June of '06?

A This meeting was done because of these problems, they are looking for better materials. And, therefore, they invited all these people who have some experience there to think about this.

Q To try to replace the Gynemesh PS mesh in Prolift?

A Yep.

Q And this is a year after launch?

A Yes.

Q June of 2006. Correct?

A Two years after the e-mails.

Q And down below, you see J. Holste and Brigitte Hellhammer.

Do you see that?

A These are two of the colleagues that are regularly at our meetings in Aachen.

Q Well, in fact, Brigitte Hellhammer, she's the woman that you had this conversation with at these meetings in 2000 about the problems that could occur if they didn't design Gynemesh PS right. Correct?

A That is the woman I talked with.



Q You see the other participant in this is Dr. Klosterhalfen who you said was a colleague of yours for the last 20 years?

A Yes.

Q Also an Ethicon consultant. Correct?

A Yes.

Q And if we could see the next slide, please.

Under the meeting minutes that -- regarding what Prof. Klosterhalfen told the group, I'd like to talk a little bit about that first line, under "Biological response to surgical mesh," where it says, "Huge surface area of meshes, in other words, more than 300 meters of suture material."

Do you see that?

A Yes, I see it.

Q Dr. Klinge, did you make the calculations of how much suture material is in this Prolift total, if we were to unravel it and string it end to end, how much suture material is in this product?

A If you stick to the same size, it is about 300-400 meters. That means about 400 yards.

Q So if you were unravel this, there is 400 yards, four football fields worth of polypropylene woven into that; is that correct?

A That is correct.



Q When he says even after 20 years the tissue is still reacting to the mesh, is that what he's talking about, reacting to these four football fields of suture material?

A Yes, that is correct.

Q Let me ask you this.

If someone comes in front of this jury and says it's sufficient that we have 50 years, 50 years of usage of polypropylene sutures in the human body, therefore, we knew the Prolift would be okay in a woman's pelvis, what would you say to that, Doctor?

A This is not sufficient to state this, because we don't have, for example, polypropylene meshes like Prolift for 50 years. We don't even have them for the abdominal wall for 50 years. We only have some sutures that are there in 50 years. So it mainly depends on the configuration of this polypropylene. So any statement just saying this polymer is safe or not safe, it doesn't meet the point. It only depends in what form this polymer is implanted in the body.

Q Does it depend on where it's going to be implanted in the body?

A And where, of course, yeah.

Q Does it depend how much of it is going to be implanted in the body?



A All this is correct. And then you have to look to the function. So you have to study it for every configuration, for every function, for every indication whether it fulfills the requirements. So, therefore, it is essential to define, to design and then to study it.

Q Is it also essential to know what the design, for instance, the pore sizes, will be if you're going to place a polypropylene mesh in a woman's pelvic tissue for the rest of her life?

A There are countless further studies showing that there are good polypropylene meshes and there are bad polypropylene meshes, and that you can show the difference in the tissue response and in the clinical behavior and the clinical outcome. So there is a huge amount of literature showing that there can be better polypropylene meshes and polypropylene meshes with a higher risk. So any statement to say polypropylene is a good guy or a bad guy, yeah, it is not helpful.

Q You have to put it in context; is that correct?

A Yes.

Q Now, you're not telling the jury that polypropylene mesh, surgical mesh, could never at any point in history be safe in a woman's pelvis; is that

correct?
A No. That is the same absolute statement that is not appropriate. So there may be some times some polypropylene structure that can be used in the pelvic floor, but it has to be designed, it has to be shown that it is like this. And in the moment, I don't know any.
Q Have you seen one for the last 20 years that would be polypropylene mesh appropriately designed for a woman's pelvic floor?
A No.
Q The next line, if you could, please, Uri, "Fibrosis is responsible for complications in mesh usage."
So the next thing that Prof. Klosterhalfen said after he was talking about these 300 meters of suture material, it says, "Fibrosis is responsible for complications in mesh usage."
Fibrosis, that's the scarring you're talking about that can occur around meshes?
A That is correct.
Q And the amount of scarring that you get, will that be dependent upon the mesh design?
A Yes. It depends from the amount of the material, from the mesh design, from the surface and from the



pores.
Q Okay. And then he mentions foreign body reaction.
Let's just talk briefly with the jury about what happens when our bodies have a foreign invader.
Next slide, please.
A So if you -- if you're injured by a foreign body, so if you get a splinter into your finger, then immediately the body tries to make a defense system there to destroy and to eliminate this foreign body. It is done by some local cells. They are building a wall around this foreign body. And they are attracting further cells, helping them. You are aware of this phenomenon because you are feeling the swelling, you are getting -- you feel some pain, you see the red skin around it. And all this is the acute inflammation if you get a foreign body, a splinter, in your hands. And if you get two, or these two splinters will be integrated into this acute inflammation.
So after one week, two week, the body may recognize that it is impossible by these small cells to remove this foreign body. Then it will go to a chronic inflammation. That means that you have a wall of inflammatory infiltrate around these foreign bodies, and outside of this, scar formation. And this scar may



build up a border between the neighboring tissues and this foreign body. And this is a situation that persists lifelong, as long as the splinter or the mesh remains in the body. So this is a permanent situation there. You have an increased remodeling, the cells are going and coming, but you have this huge amount or this amount of scar tissue as a border between this foreign body and the neighboring tissues.
Q And how is the amount of scarring related to the amount of the foreign body?
A It's quite clear, the bigger the foreign body, the bigger the inflammation. And the bigger the inflammation, the bigger the scarring. That can clearly be shown, and this is true for many diseases as well, not only for foreign bodies.
Q When you were talking about scarring, especially when it comes to the scarring that forms around Gynemesh PS, once a scar --
A -- ever -- always a scar. There is no way to -- by the body to remove this.
Q So when we're talking about these foreign bodies, explain to the jury about this inflammatory process and the scarring as it relates to the diagram you see in the middle, if you could just explain the diagram and then explain from your standpoint why this



is important when it comes to surgical meshes?
A You see in this image a cross-section of the sutures, two sutures are coming directly to you, and there is a cross-section. So the circle in the middle, that should be the suture --
Q Dr. Klinge, would that be like if we're looking at the end of the mesh and we're looking at the fibers coming right at it?
A Yeah. Or when you cut it. When you cut it through, then you will see it like this.
Q Okay. Go ahead.
A And every filament is surrounded by this inflammatory infiltrate and by this fibrotic capsule. And if these are -- if you have a large distance between these two filaments, then the space in between can be filled by fat tissue or what is there in this area by the normal physiological tissue. But if these filaments are going close together, then there will be some distance where all this together, the two splinters, will be integrated into one wound altogether will be circulated by scar tissue and even the space in between will be filled by scar.
Q And is that space filled between, is that what the jury has heard about bridging fibrosis?
A The space in between the filaments, that is the

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pore. And if this is filled by scar tissue, this is what we would call or we call -- that is the bridging fibrosis.

Q And, again, when you were talking about if the fibers are far enough apart, it just has the scar or the granuloma around each one, what is that distance that there has to be, based upon your 20 years of work, when it comes to these pores?

A For polypropylene, at least it has to be 1 millimeter to avoid this filling of the pore by scar tissue. If you don't want to have it, you have to take care that the filaments are -- that the distance between the filaments is more -- even far more than this 1 filament.

Q And I know you said before that your work from 2000 on with Ethicon, they were aware of this 1 millimeter requirement. Correct?

A This is correct. This has been published, and Prof. Klosterhalfen just refers -- he's -- yeah. He repeated these results of these years where we studied it.

Q He repeats it at this expert meeting where they're trying to look at the problems with Gynemesh PS?

A Yes.

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Q So the jury has heard small pore, large pore, they've heard words like macroporous, microporous. Forgetting the words for a moment, what's the important thing for this jury to know in terms of whether or not a pore will be large enough to prevent fibrotic bridging, scar plate, shrinkage and complications for a patient? What is that distance?

A The main message is it is critical, the pore size is critical for the outcome, and it should be at least, as you stated, 1 to 2 millimeters.

Q This will allow this fatty tissue to grow in?

A And then you have a flexible mesh heading off these scar plate that, when it's contracted, it's coming -- it's becoming stiff and like leather, so you don't want to have this.

Q And you have felt explanted mesh and what it feels like to have this scar wrapped around the fiber that has to be taken out of a patient. You've felt that. Correct?

A Yeah. We have collected in our department, meanwhile, more than 500 explanted meshes from humans. And Prof. Klosterhalfen, he has, meanwhile, more than 4,000 of these. And if you look to these explants, many, not all, but many of them are looking very, very

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stiff, like leather.

Q Next slide, please.

At the end of this June 2006 expert meeting in Norderstedt, where Ethicon was looking at the problems with Gynemesh PS and looking to replace it, what were these -- what does this section, "Unmet clinical needs," tell you, Dr. Klinge? Is that significant to your opinions?

A There -- it was the definition of the major problems. And if you remember the e-mails from 2003 and 2004, they mainly take up the message again. So, in the center, what has to be done was to design material with no shrinkage, fibrosis reduction and severe contraction. And this was the highest priority. So it was very clear what should have been done. And this was expressed in this table in 2006.

Q Let's go to the next slide, please, Uri.

2007, a year later. Another expert meeting in Norderstedt. Correct?

A It is correct, yes.

Q Many of the same participants. Correct?

MR. GAGE: Objection, Your Honor.

BY MR. ANDERSON:

Q Does this have many of the same participants --

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THE COURT: There's an objection.

MR. ANDERSON: Oh.

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(The following occurred at sidebar:)

MR. GAGE: This meeting comes six or seven or eight months after Linda Gross's surgery. So in terms of this particular expert and in terms of what the company was discussing, et cetera, it's post-dating the surgery, and we would object to it on that basis.

MR. ANDERSON: This is the scientific development, or lack thereof, of making any changes to the Gynemesh PS despite the fact that they repeated to see problems. It shows a lack of this company doing anything from one year to the next to the next. They continue to sell and market a product that had been told by this expert for years, you can't do this. It's a problem. They were told --

THE COURT: But they can't -- first of all, we're not into a punitive phase where we're talking about that they continued to do something they knew was wrong.

Second, other than that, what does this -- other than their bad conduct post her surgery, what does this add?

MR. MAZIE: It goes to Dr. Hinoul's

admission that they knew everything in the beginning. So anything that was discussed there is a reiteration of everything they already knew. And it's just proof of what they knew early on. He's already said we knew everything, every complication, every risk.

THE COURT: You can ask him about what was discussed at the meeting as long as you can tie it into this was already known in 2005.

MR. ANDERSON: Absolutely, it will be, Your Honor. And, again, it's already in evidence, the part I'm going to show.

THE COURT: Okay.

MR. ANDERSON: Thank you.

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(The sidebar ended.)

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BY MR. ANDERSON:

Q Put the slide back up, please.

We were talking about the fact that these are the same participants.

And what's your understanding of why this meeting was happening almost a year later?

A Almost the same participants. It's the same problem, they are still looking for a better material.

Q And did you see the PowerPoint that was



presented by one of these individuals, I think it's Kirsten Spychaj? Did you see the PowerPoint presentation that she gave at this meeting?

A Yes, I've seen it.

Q Uri, if we could show that. I believe the jury has seen it.

MR. ANDERSON: This is P0753. I believe it is already in evidence, Mr. Gage.

MR. GAGE: Your Honor, just the same objection as I repeated just a second ago.

THE COURT: The objection is preserved for the record, Counsel.

MR. GAGE: Thank you.

THE COURT: You can proceed.

MR. ANDERSON: Thank you.

BY MR. ANDERSON:

Q "Factors related to mesh shrinkage, what do we know? A review of literature and internal studies."

"Pore size. Small pore meshes, less than 1 millimeter, lead to fibrotic bridging," which we were discussing with the jury where it scars across these holes. Correct?

A Yes, that is correct.

Q "Increased shrinkage."

What does that do once it covers the holes?



A Scar tissue, if it matures, it is losing 20 percent of the water, and, therefore, it is getting closer together. And it -- if there is a mesh in between, it will shrink together, it will push together, it will fold it. And, therefore, if you have smaller pores, you will have more scar tissue, where you will have more shrinkage.

Q If we could look at the next slide.

The unmet needs here again almost a year later, 2007, another expert meeting. It says, "The following summary of unmet needs generated June 2, 2006 was again confirmed without any adding."

Is that significant to your opinions in this case, Dr. Klinge?

A Yes, yes.

Q Why?

A At the top was again confirmed. So this is a copy and paste. Nothing has changed. And there was no information what really has been done to improve the configuration of the mesh.

Q Okay. Now that we've talked about the work that you've done about pore size, now that we've talked about Ethicon's knowledge about pore size prior to launching Prolift, I would now like to focus the jury's attention on the pore size and the pore geometry of the



Gynemesh PS in this mesh. Okay?

A Yes.

Q Next slide, please.

On the left, I wanted to bring up a photo that the jury saw last week from your colleague, Dr. Muhl's testing.

That's an arm, arm number 3 of a Gynecare Prolift total. Correct?

A Yes, that's correct.

Q And then what are we seeing on the right there, Dr. Klinge?

A On the right you see this mesh in higher magnification, and it is converted into a black/white image. And all these black structures represents the filaments. And you see that there are a lot of different pores, so spaces in between the filaments, here is a larger one, here are a smaller one and here are a lot of very, very small one. So when you implant this into the tissue, then the body reacts with a foreign body reaction, sends the cells and sends the scar tissues around these filaments.

So after incorporation and implanting this in humans, then you will see that a lot of these filaments get surrounded by these foreign body reaction. And what we found out in many, many, many

studies is, in these very small pores there, there -- these are completely filled with scar tissue. And you need a huge difference or distance between the filaments.

And at this image, you see the structural problem of this mesh, because you see that in almost all of these pores, there are crossing some other filaments and they are bringing the scar formation into the pores. So that means that you have a significant reduction of really large pore areas that are free of scar tissue.

And this is the -- this can -- or this explains very well why would this structure after integration into tissue you have a problem with extended scar formation, because all this area will be integrated into scar tissue, and then you have here pores that are at the limit. If there is something changing through these pores, again, even this area will be surrounded by scar tissue.

Q You mean any changes --

A Any changes of these pores will increase the risk for scarring reaction.

Q So if minimal stress is placed on the mesh and the pores begin to collapse, it's even worse?

A Yeah. So in regards to the risk for scar



formation and shrinkage and all these complications there, it maybe would have been better not to have these crossing filaments. But it has to be tested, because it has a lot of consequences to the biomechanical of all these things that has to be studied there, but here you see that is the main problem in regard to the clinical outcome. These are the crossing filaments, the crossing bars or whatever you like to name them.

Q And as we were looking at those photographs, the diagrams where you could see the end of the fibers with the granulomas around it?

A Yes.

Q Will there be scarring around each and every fiber of polypropylene throughout this entire piece of mesh?

A If you are looking with a microscope, you will see around every fiber at every area, you will see some inflammatory tissue around and some scar formation around. And in the smaller pores, you will see that they are filled by scar tissue. You will not see significantly amount of fat tissue in these pores, and that makes it stiff. So that is --

Q And leads to shrinkage?

A And shrinkage and other consequences of excessive



scar formation in soft tissue.

Q If someone were to come before this jury and say that pore size of 75 microns is sufficient in order to avoid scarring, in order to avoid scar plates, in order to avoid shrinkage, what would you want this jury to know, if someone stands before them and says 75 microns instead of 1,000 microns is safe?

A I've recognized that there is a discussion in all the many documents about these 75 microns. This derives from the publication from my friend, Parviz Amid who was living in Los Angeles, and he was the first in 1997 who thought about pore size and proposed a classification of hernia meshes based on pore size.

But his focus was the risk for infection, because at that time, there were textile structures with some pores in comparison to some mesh materials without any pores. And we knew that they have an increased risk for infection. So, therefore, he said if you have pores of more than 75 microns, you have a lower risk of infection than if you don't have them. That was the basic reason for this. 75 microns. The size of the filament is around 90, 85.7 microns.

Q The filament, just one of the polypropylene fibers, it's already 95 microns?

A Every line here has a width of 90 microns. So we



are talking about pores that are smaller, as every line here.

Q Can you find a pore that is 75 microns in size even in the knotting?

A Yes. You have to look -- to measure it and look precisely whether it really fits the 75, but from all what we know is a pore of 75 microns, this is filled not even by scar formation, just but -- by the inflammatory infiltrate. And -- but it never will be filled by fat tissue. So it is not a good cutoff to define a good pore from a bad pore. But, furthermore, it is not adequate to say a mesh with one pore size. You never have a mesh with one pore size. You see in this figure very clear that you have a huge variety. You have big pores, you have small pores. And there is no mesh without these pores of 75 microns, because you have these bindings, you have these knots. So, therefore, it is necessary to measure it and the variety of all these pores as well. But the cutoff of 75, it's not predicting the risk of scar formation. It's meaningless.

Q Was that a classification in the late '90s that was classifying the -- you mentioned for the jury the older, heavier weight, small pore meshes?

A Yes. It was written at that time because we

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started later on to produce these large pore meshes with 3 millimeter and 5. So he didn't have it at that time.

Q So he didn't have the large pore, lightweight meshes in order to look at and determine what the proper pore size was?

A Yeah. But he even didn't look to the tissue response to the bridging fibrosis. That was not a term he was looking at. He was mainly focused on infection.

Q And with your publications from '98, '99, 2002 forward, was the scientific community then aware of the necessity of greater than 1 millimeter pores in order to prevent this bridging?

A There was a permanent discussion that we need a revised classification of this, because as you said, most of the meshes meanwhile have pore size that are far beyond, and it was not considered any longer as a critical cutoff.

And, therefore, we proposed or we changed or we -- no. We give a proposal of the new classification that predicts the risk for this bridging fibrosis later on.

Q Okay. So if someone were to come in front of this jury and say that 1 millimeter pore size, Klinge's work, 20 years of this information, we don't

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buy the 1 millimeter pore size, let me ask you, in the worldwide peer-reviewed literature since this concept came out in the late '90s, early 2000s by you and the group at Ethicon -- you and the group at Norderstedt with Ethicon, have you ever seen anywhere in the scientific literature anyone who has refuted or disputed or who has been able to state that you were incorrect with greater than 1 millimeter?

A I never got aware of data that are in contradiction to this message. The term "large pore" is better than small pores, I think there are numerous citations in the literature. It's well accepted. And even in the many records from Ethicon I reviewed, I saw these terms of large pores is necessary. They are adopted in these presentations in these documents. And I've never seen a sentence where they say no, it's not. And I've never seen, and you can believe me, if it's wrong, science will lead to publications that will show that you made a mistake. So I never saw a -- someone who could prove by data or by looking with a microscope to the tissue response that this 1 millimeter is not right.

Q We're going to talk about the testing that Dr. Muhl did and that he spoke to this jury about last week. I'm going to talk about that in just a couple

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minutes.

But before we do, based upon the testing that you did and the results that he had from that test, what percentage of Gynemesh PS would be covered in fibrosis or scar tissue?

A It's almost 75 percent.

Q 75 percent of this would be covered in scar tissue as a result of the pore size?

A If you placed this in the abdominal wall in a plane fashion, if you plane it in a three-dimensional fashion, by every bending, the pore size will go even down. And if you play -- if you apply some sort of tension there, you will see a deformation of the pores, because the polypropylene itself is not an elastic material. It is just -- any elongation is just done by deformation by the pores. That means they will become smaller, and, therefore, the percentage of bridging fibrosis will increase even more. So if you place it tension free in the abdominal wall in a plane area, 75 percent is the correct.

Q I want to talk about even before any tension is placed on this mesh, do you have an opinion, based upon yours and Dr. Muhl's testing regarding the fact that 75 percent of this would be covered by scar tissue, do you have an opinion that just that design

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alone would be unsafe in a woman's pelvis permanently?

A As I said, there is a structural problem of this design because of these crossing filaments.

Q Even before we talk about putting any stress on the product. Correct?

A Yes. Even before this. If you leave them off, if you remove these filaments, the scar formation will be less.

Q Let's talk a little bit.

Did you have an opportunity -- from your review of all the documents and the deposition testimony, did you have an opportunity to learn how it is that Ethicon was trying to test pore size prior to launching Prolift in 2005?

A Yes, I did.

Q Well, wait. Look over to the right of that diagram.

Do you see that?

A Yes.

Q And it says pore size in millimeter squared, and they list a variety of different pore sizes.

2.3, these -- this listing, what's your understanding as to what they were doing there?

A So obviously they are looking to some few cells,

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and they are trying to measure the area, the total area. That means the total number of white pixels in this area. And this means that you have an area -- and if you made a -- if you assume that it is a square, you can calculate the root out of it, and then you may have an estimate of the pore size.

But this is not correct, because everyone can see that it is not a square. These are irregular forms of it. So the measurement of the area, the calculation of the area is one thing that has been tried to find out what is the percentage of good pores there. But it's not very precise.

Other ways has been that with a ruler, you just took out some of these pores and tried to measure the distance.

Q I need to orient the jury.

You said that one way that Ethicon was looking at pore size prior to launching Prolift was they were just trying to calculate a square area. Correct?

A Yes.

Q A second way that Ethicon was looking at measuring pores prior to March 2005 was how?

A That was done just by -- with a ruler, where you measure the distance here in between, and then maybe

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you get a figure of 2 millimeters or so. But this is not represented to reflect the percentage of good pores in such a mesh structure. It just gives one diameter in one pore, so this is not sufficient to get any information how good a mesh will perform in the body.

Q Does the pore have to be 1 millimeter in diameter?

A To every side. It has to be at least, at least 1 millimeter to all sides.

Q So is the manner in which to properly test this to see how many 1 millimeter diameter spheres will fit into any of these holes?

A That is eventually the procedure that Prof. Muhl put to an automatic analysis, yes.

Q Can I see the next slide, please?

In discussing this pore size specification, it seems like a lot of data up there. But is this concept of pore size critical to the Gynemesh PS and your opinions?

MR. GAGE: Your Honor, same objection to the showing --

THE COURT: Your objection is preserved but overruled.

BY MR. ANDERSON:

Q Before we get into this data, is pore size

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critical in your opinion in order to determine whether or not this would safely be implanted in a woman's body?

A Yes, yes.

Q So we were talking about some information that you had with regard to how Ethicon said that they were measuring their pores. An e-mail from Scott Ciarrocca to Dan Burkley.

Did you understand Dan Burkley to be the person at Ethicon who was in charge of measuring pores on Gynemesh PS?

A Yes, I did.

Q "Susan Lin informs me that you have" -- this is Ciarrocca to Burkley.

"Susan Lin informs me that you have a visual technical manual for measuring mesh pore size. Is this a documented standard and is it used in production or development, or is it just employed to compare our mesh to competitors?"

Did I read that read?

A Yes.

Q Let's see what Dan's response is to Ciarrocca.

"That is not exactly correct. I developed a procedure for measuring porosity many years ago when

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one of the mesh teams at the time asked me if I could measure porosity. I asked them, what do you mean by porosity? I didn't get a response from any of the nine team members, so I defined my interpretation of porosity and how I could measure it, which turned into" this number over here. "That represents the amount of open space in mesh, which I define as a percentage of porosity. It can be measured a number of different ways. This procedure won't be appropriate for all meshes. There is no written test method or procedure for pore size."

Was that your understanding, that before Gynemesh PS was launched, that Ethicon did not have a written standard or test method for looking at pore size?

A Yes.

Q "Pore size could be measured, but I've asked members of mesh teams what they want when they have a mesh that has different sizes because of construction, such as Prolene Soft Mesh."

And that's what we just were looking at with the jury, right, the pores are all different sizes. Correct?

A Yes. This is the third possibility to get a figure about porosity.

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Q Okay. Just one second.
"Many don't know and a few ask for all the different pores in the construction, which is a challenge.
"All examinations have been done for research purposes for competitive assessment. None have been performed to compare to a specification, nor, to my knowledge, has a specification been created."
And this was being sent in 2009. Correct?
A Yeah.
Q So was it -- is it your opinion that prior to Prolift being launched in March of 2005, that Ethicon did not have a specification for measuring pore size?
A Yes, that is correct. This procedure that is proposed there is just the relation between white pixels and black pixels and is not focused on the pore size. It is not able to do so.
Q This method just tells you the percentage of open space. Correct?
A Yes.
Q And then the other method that you saw that some people at Ethicon were using was just a line to go across the pore to say, oh, this is how long I think it is?

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A Yep.
Q And the other way was to say let's see what the area is in the square area in these things that are not square. Correct?
A The letter is what we would call today the textile porosity, but it's not accurate as well.
Q Would any of these three methods that Ethicon seemed to be using prior to March 2005 tell you anything about how many 1 millimeter pores you have in all directions?
A No, none.
Q Would any of these test methods tell you how many greater than 1 millimeter pores are distributed throughout the mesh?
A No.
Q Would any of these test methods tell Ethicon what would happen in a woman's pelvic tissue for the rest of her life with regard to these pores with bars between them?
A These techniques or these procedures are not sufficient to predict this risk.
Q So prior to Prolift being launched in March of 2005, from the documents you've reviewed and these different test methods that you've looked at, do you have an opinion as to whether they had any idea whether

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they had greater than 1 millimeter pore size in Gynemesh PS, and if so, over how much of the product? Did they know?
A They knew that it was important, but they didn't know what happens in this textile structure in this place.
Q Because they didn't measure it. Correct?
A They didn't know to measure it.
Q Next slide, please.
Another e-mail, this is in June of 2006, a year after Prolift is launched, from Bob Rousseau to Scott Ciarrocca, "Pore size in microns was not measured during the development of Prolene Soft Mesh. The total percent area that is open was measured and is considered an accurate method. Since the product construction results in irregular pore geometries and sizes, it is not accurate to report a distinct pore size."
Did I read that correctly?
A Yes.
Q So if someone comes before this jury and says we meet the 1 millimeter in all directions pore size requirement because we have 2.5-millimeter pores, if someone gets in front of this jury and says we have 2.5-millimeters pores, what you would say?

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A Anyone who is coming here and saying we have a mesh with one figure of pore size, that is not true, because everyone will see or can see that if you look to this image of the pores, that you always have a mix. You have many variation of these pores.
So the critical information is, what is the area of the good pores in relation to the mesh area? And, therefore, it is necessary to measure exactly the pore -- every pore.
Q And based upon the amount -- based upon the information that you have and the testing that was done, what percentage of good pores were there in Gynemesh PS even before strain was placed?
A It was around 7 -- 25 percent.
Q So 75 percent would be bad pores?
A Yes.
Q 75 percent would cause fibrotic bridging?
A Will cause -- will be bridged by scar tissue, yes.
Q Scar plate?
A Scar plate, shrinkage.
Q Shrinkage?
A And so --
Q So if someone has a Gynemesh PS implant in them in the form of a Prolift and they have retracted

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arms of the mesh, is that explained by improper pore size, fibrotic bridging, scar plate and shrinkage?
A Yes.
Q If someone has bunching of the mesh that is causing pain and other problems, and they've been implanted with a Gynemesh PS Prolift, is this an explanation as to why that would occur?
MR. GAGE: Objection. I don't believe there's a sufficient foundation, Your Honor.
THE COURT: The objection is overruled. I'll allow him to answer from his view as an engineer.
Proceed.
BY MR. ANDERSON:
Q You've seen in the literature and other places that sometimes it's called bunching, sometimes it's called contraction, sometimes it's called shrinkage. Correct?
A Yes.
Q So if someone had what was described as bunching of the mesh that's been implanted with Prolift, would that be explained by improper pore size, fibrotic bridging, scar plates and mesh shrinkage?
A Yes. All these problems that are related to excessive scar formation are explained by this structural disadvantage.

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Q Thank you. Slide 15, please.
Is this what we were just discussing, that effective porosity, after you account for the pores that will have 1 millimeter in all directions based upon Dr. Muhl's report, that this will only have effective or open pores of 26 percent?
A Yes. Effective porosity, that is the area of the good pores, to say it simple.
Q Dr. Muhl was asked by defense counsel last week why it was -- well, strike that.
Defense counsel asked Dr. Muhl a number of questions last week that he couldn't answer because he said I'm not a medical doctor, you'll have to ask Dr. Klinge. Okay?
A Thank you.
Q So I want to ask you some of those questions today. Okay?
A Yes.
Q I don't think it bears repeating, but obviously the reason that you told him to have the machine automated to look at Gynemesh PS and to find the 1 millimeter pore areas is because of everything that we've been discussing this morning regarding the critical pore size of 1 millimeter. Correct?
A Yes. The advantage of his procedure is that it

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can be done automatically. It is a lot of work to do it by hand, to look whether these pores are big enough, so he proposed an algorithm that a machine can make an analysis of all these pores automatically within some minutes.
Q But even though it may be a lot of work, prior to March of 2005, Ethicon, Dan Burkley and these others, could have measured the pores to see how many of them were greater than 1 millimeter in all directions, couldn't they?
A They could.
Q There was software available as well that could have done that for them. Correct?
A They could have done it. There is no real invention in this measurements of Muhl.
Q What you and Prof. Muhl did in that work between 2005 to 2007 was just an automated way to count the pores --
A Yes.
Q -- and see how many were larger than 1 millimeter. Right?
A They applied what we otherwise would have to do by hand, that this was done just by a computer program.
Q But in the e-mail from Dan Burkley when he said some of the team members have asked me to measure

3474

all the pores but that's a challenge, just because it was a challenge didn't mean he couldn't have done it. Correct?
A Yeah. But if he -- when he ask what may be the reason, what do you think what is important with pores, and none could answer this, I think that is an explanation why they didn't go on further.
Q Let's look at the next slide, please.
You've seen this from Dr. Muhl's report as well?
A Yes.
Q Explain at the top, this is Prolift arm, and we have different amounts of tension.
Can you explain to the jury why you chose these four different amounts of tension, from zero to 1,000?
A When we decided to apply some tension to these textile structures, we have to define what range should be applied to these structures. And one critical point was that we knew from our previous work that beyond 20 newton, that means 2 kilogram per centimeter, that the tissue is going to rupture. So we are convinced that we don't need any textile structure that is stronger than the neighboring tissues. So the upper point was 20 newton.

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So the next point was that we wanted to have a certain elongation of the mesh. And we have, according to the studies in the literature, that we should have been or there should have been expected an elongation, if it's placed in the tissue, by about 20 percent. This should be comfortable, not to hinder the mobility of the tissue very much. But it's a rough estimate about it. But we wanted to have an elongation of 20 percent. And we have seen that Ethicon, they expected that during the implantation, there was applied some sort of strain to this material to the arms. And we wanted to stay far below.

And, therefore, the reason was, and we wanted to have very simple numbers. And, therefore, we decided to place a load of 1 kilogram, 500 gram, 250 gram and to look what happens there to the textile structure to see whether the one is better than the other.

Q So with the first slide that -- the slide before this that we saw, that's where the machine has no force on the Gynemesh PS and it's just calculating how many pores there are that are greater than 1 millimeter in all directions. Correct?

A That is correct.

Q And that was only pores -- I think

3476

26 percent?

A 26 percent of the pores.

Q Then when you applied these various forces, Prof. -- Dr. Muhl did this in his machine, what happened when 1.65 pounds of force was placed on arm 3?

A If you apply a mechanical load of 500 gram or 1.6 pounds, then the good pores disappeared completely. So that means when you place this mesh in an area where this load is applied, at some time, for however, in this moment, the good pores will disappear, and then a complete fibrotic bridging of the entire mesh area will occur.

Q And Dr. Muhl was asked by defense counsel, well, why did you use uniaxial testing, pulling it like this?

Can you explain to the jury why this was part of this test?

A Yeah. Because multiaxial is really not possible. But this was not intended to make a simulation of the pelvic floor and of the many different forces. We know that the arms are stressed in a uniaxial way, because it is stretched only from one side. We know that ligaments mainly are stressed in a uniaxial way. So, therefore, we are convinced that to get an impression about the stability of the meshes to withstand some

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mechanical stress should be done, first of all, in a uniaxial way.

Q Is this something that Ethicon could have done before March of 2005 with the Gynemesh PS, and that is to look at what the pores would look like under some minimal strain?

A To put strain or a mechanical load to a mesh, it is nothing that couldn't have been done.

Q In your opinion, should Ethicon have looked at the effective porosity, the amount of open pores after 1 millimeter, and should Ethicon have looked at those pores after some minimal amount of strain before selling this to be permanently implanted into a woman's body?

A Yes. Always when you intend to use a mesh in an area where you cannot rule out that it is really tension free, that there occurs some mechanical load, you have to look what happens to the pores in case the stress will appear.

Q Was Ethicon aware of a study that you and Prof. Muhl had done in 2007?

Next slide, please.

MR. GAGE: Same objection, Your Honor, just preserve the record.

BY MR. ANDERSON:

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Q Before we get to that, did you have an opportunity to look at the Ethicon documents to see what they estimated the forces to be that would be placed on the arms?

A Yes, yes, I've seen it.

Q And one of them says 5 pounds of force?

A Yes.

Q And the other area was 12 pounds of force?

A Yes.

Q And what were the pounds of force that we just said at 1.65 pounds, what happened to the mesh?

A 1 -- yeah. At a load of 1.6 pounds, the good pores disappeared completely already. So it's far below these values.

Q Next slide, please.

And is that what's represented here in the Muhl finding, that over here under 3.3 pounds, it turns into that configuration?

A Yes. And this image clearly shows that the elongation is done by deformation of the pores.

Q And at even half that, which was 500, at even half of that, 1.65, there was zero effective porosity. Correct?

A Yep.

Q Nowhere for the body to allow fat tissue

3479

ingrowth to make it flexible?
A No.
Q Only places where scarring would come into the pores and encapsulate this mesh in rigid scar plate. Correct?
A That is correct.
Q Leading to shrinkage?
A Shrinkage.
Q Leading to patient complications?
A Yes.
Q Next slide, please.
I was asking you before if out of the documents you reviewed, whether or not Ethicon was aware of this testing and this article that you and Muhl had published in 2007. I believe the jury saw this one the other day.
"Interesting article that may give us some guidance on what we measure on the mesh characterization. Aachen has a very sophisticated setup but does address the question of what should be measured and what is the relevance of the measurement."
Have you seen that document?
A Yes, I've seen it.
Q The next document please.
Yeah, it's right there.

3480

"Hi, Marty, I just got my hands on this article on porosity and thought you might be interested."
You've seen these documents?
A Yes.
Q Next one, please.
And you've seen this by -- this e-mail from Joerg Holste.
And who was Joerg Holste?
A Joerg Holste was, for 30 years, one of the principal investigators at the R&D department for Ethicon in Norderstedt.
Q Did you work closely with him over the years?
A For many years we did.
Q And do you understand Juergen Trzewik, who he is sending this e-mail to, is the top biomechanical engineer at Ethicon?
A At that time, yes.
Q And he forwarded it to him, your article. Correct?
A Yes.
Q Go to slide 22.
Did you see in the Ethicon documents that you reviewed, Dr. Klinge, that they were aware of the

3481

importance of looking at pore size after stretch was placed on their meshes?
A Yes.
Q And how is this significant to you, this number 4 that we have called out?
A In this document, it is clearly that they recognized and they accepted that the requirements for the good mesh, that this came out of the new projects which were initiated to find a better material, and the requirement was defined as pore size of more than 1 millimeter under stretch. And that means that without stretch, you should estimate -- or you should go to a pore size of more than 3 millimeters. That has been defined as optimum requirement for a better mesh.
Q So no matter what your pore size is that you start out with, if you're going to put sufficient strain on it, no matter what that strain is, you need pore sizes greater than 1 millimeter after that. Correct?
A Yes.
Q And you need pore sizes greater than 1 millimeter to keep this scar tissue from growing in. Correct?
A Yes. That is their definition of good mesh, and it is quite clear that the Prolift will fail such a

3482

test.
Q So they're looking at this in 2008.
Had they done it in 2005, Prolift would have failed?
A They would have exchanged it by another.
Q Next slide, please.
There is some question as to whether or not Ethicon was aware of the concept of effective porosity. I want to show you this document from August 2008.
What do you see there on the left?
A On the left side, you see almost exactly that is the test I did with Prof. Muhl. You apply the mechanical load to a textile structures. So this is done -- this is in total agreement to our understanding what is important, that you need these pores, that you have to guarantee that even under mechanical load you have these good pores. And they did it.
Q They did it three years after the product was launched?
A Yes. But this means that there is no contradiction in the content of this, what we have studied for 20 years. So these are not data that are showing that we are -- that we are wrong in this. So it is very clear, this concept still is valuable and it is still accepted in Ethicon as well.

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Q Do you have an opinion as to whether or not Ethicon should have done this for Gynemesh PS prior to putting it on the market in 2005?
A Definitely. It was quite clear that you need large pores at that time point. And, therefore, you have to measure it.
Q You mentioned before when talking about the various forces and why you chose the forces in the uniaxial fashion, first of all, that would be force in a uniaxial fashion on one of Ethicon's meshes. Correct?
A Yes.
Q And when you said you chose something less than 2 milligrams of force because you said most tissues will rupture above 2 kilograms of force. Correct?
A That is correct.
Q You guys used half of that, which is what's represented in the middle picture up there. Correct?
MR. GAGE: Objection, Your Honor. Leading questions.
MR. ANDERSON: I'll withdraw it.
BY MR. ANDERSON:
Q Is that in the middle half of the top amount of what you used in the other testing?

3484

A Yes.
Q And they used double -- strike that.
Did they use double that amount in the bottom drawing?
A Yes. But I think it will depend from the indication which load has to be applied there. So I think we are in a good range there.
Q Next slide, please.
Show the jury an e-mail that they saw a couple weeks ago, maybe even on Friday. 11/23/05. This is an Axel Arnaud e-mail regarding information that was being given by a Prolift surgeon, Dr. Eberhard.
And this is eight months after Prolift was launched. Correct?
A Yes, that is correct.
Q Number 5, he, Dr. Eberhard, is reporting to Axel Arnaud, "He believes that after retrieval of the cannula, the straps take a rope-like shape which is not optimal in his opinion. He has observed that some patients have discomfort as they can feel the straps with Prolift." It says, "The Perigee implants lie flat."
Why is this significant to your opinions, if at all, Doctor?

3485

A It demonstrates that there is a concern that the arms will not -- even at that time point, will not preserve its structure when it's placed into the human body.
Q And if we have curling and roping and pore deformation of -- strike that.
If there is curling and roping and pore deformation in the arms going through a woman's groin and through her buttocks, do you have an opinion as to what will occur after she goes home from surgery and for the rest of her life with this mesh in her?
A If you have these curling and shrinkage, there is no chance for any place in the arms to be filled by fat tissue, but this will incorporate it into scar tissue completely.
Q Is that dangerous for the patient?
A That is a safe concern -- a safety concern.
Q Let's see the next slide, please.
Dr. Klinge, you've seen the implantation videos, the training videos by Ethicon. Correct?
A Yes, I have seen it.
Q Can you play this short clip?
MR. GAGE: Objection, Your Honor. Can we approach?
- - -

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(The following occurred at sidebar:)
MR. GAGE: I'm assuming they're going to show the arms and show the roping and curling. This is exactly the testimony that we went through with Dr. Weber, and it's cumulative between the experts, and I would ask that it not be done.
MR. ANDERSON: This is the top biomaterial scientist in the world that worked with them. He has now gone through and described that Muhl has --
THE COURT: I'm going to deal with it briefly.
How much longer are you going to be?
MR. ANDERSON: Five minutes, ten minutes.
THE COURT: Because their lunch is here.
So do the rest and then we'll break.
MR. ANDERSON: Thanks.
- - -
(The sidebar ended.)
- - -
BY MR. ANDERSON:
Q I'm sorry to have to show this again. And we're just going to show a brief clip to demonstrate what we've been talking about here. Okay?
A Yep.
Q Can you show that, please?

Do you see the arms over on the right coming out of the woman's groin, Dr. Klinge?
A Yes.
Q And do you see the ones on the left coming out?
A Yes.
Q Explain what you are seeing here in terms of what we've been discussing, curling and roping and these problems that could occur as a result.
A Yeah. You see in this video that the arms get curled, that they are -- the appearance is a rope there.
Q And as that rope comes through the tissue, would you expect that these polypropylene arms here will just magically spring back out flat like this?
MR. GAGE: Objection, leading.
BY MR. ANDERSON:
Q Would you expect from this diagram right here as those arms are laying in the woman's groin and curled, would you expect those to pop back into shape?
A No, no, no. Certainly not.
Q Explain that to the jury, please.
A Certainly not. The power of these small 5-0 polypropylene fibers to spring back into original form is quite low. So if you place this in this rope form



in the tissue where all the tissue around is going to this one, there is no sufficient force to say, okay, I push the cells back again and then I'm coming to a plane -- to a plane shape again. So it is not reasonable, for my experience not.
If you believe in this, you should try to test it and to study it. But I have serious doubts that it will not be possible if you have a rope mesh, then it spring off again. That would mean in the field of abdominal wall hernia, if you place a hernia mesh there in a -- yeah, a wrinkled form, that the surgeon should not concern any longer because it's springing up again and it's lying flat. No, it's not like this. So if it is placed in this configuration in tissue, it will stay there. That is my opinion to this.
Q From all the documents that you reviewed, did you see anywhere where Ethicon tested what would occur due to this roping prior to launching the Prolift in March 2005 for this product to be permanently implanted into woman? Did you see that anywhere?
A I didn't -- no, no.
Q In your opinion, should Ethicon have tested to see what would happen to the arms after it was curled and roped like this and going all the way through a woman's groin and through her buttocks?



Should they have tested that?
MR. GAGE: Objection, leading, Your Honor.
THE COURT: The objection is overruled.
You can answer.
MR. ANDERSON: Thank you.
THE WITNESS: If the arms are looking like this, it is necessary to look what happens in the tissue with these arms. Because -- or you should develop another textile structure so that the arms look different than this one. But you have to do something.
BY MR. ANDERSON:
Q Do you have an opinion, Dr. Klinge, if what the jury is seeing with this roping in the arms is similar to the roping that you and Dr. Muhl saw when you did your testing on the mesh?
A Yes. It's quite similar appearance. And you don't need even a microscope. Everyone can -- if you take the arms and put some mechanical strain to it, you will see this deformation of the pores, so --
Q At the strain of either 5 pounds of force or 12 pounds of force or some greater force as was stated by Ethicon?
A This happens by comparatively low forces. And this has to be studied in relation to the indication where you place it.



Q Last slide, please. Can you highlight that part?
You've seen this document. Correct?
A Yes.
Q "Jennifer, I'll just weigh in on this specifically designed synthetic mesh. This mesh was not specifically designed for Prolift application. We pulled it out of our existing bag of tricks. So a statement that it's specifically designed is unsupportable from a design history standpoint."
Do you see that?
A Yes.
Q Dr. Klinge, do you have an opinion as to whether or not it is sufficient to take a hernia mesh that's been adapted for hernia use and to sell it for pelvic floor use without proper testing?
A Yes.
Q What is that opinion?
A I think that it is not sufficient. And I thought we made it clear by all our experiments that you have to make -- find a specific design for the specific indication in a specific area, and, therefore, you have to define the requirements specifically for this purpose. And it is not suitable or adequate to just put from one area in the body a textile and place it in

3491

another.
Q Three more questions.
Based upon all of your work for 20 years, your work in the industry, all of your publications and your career in looking at surgical issues related to surgical meshes, biomaterials science, tissue response, histopathology and your work in this field for 20 years, as well as your review of all of the materials you saw in this case related to the depositions and the internal documents by Ethicon, do you have an opinion as to whether or not Gynemesh PS in the Prolift is a defective product?
A Yes.
Q And what is that?
A It was a defective product.
Q Do you have an opinion as to whether or not the Prolift/Gynemesh PS was unreasonably dangerous when it was sold in March of 2005 to be permanently implanted into women?
A Yes.
Q And what's that opinion?
A It was dangerous.
Q Do you have an opinion as to whether or not Ethicon should have ever sold Prolift with this Gynemesh PS in it in March of 2005?

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A Yes.
Q And what's that opinion?
A They should never have sold it.
MR. ANDERSON: No further questions at this time, Your Honor.
THE COURT: Okay. We'll break for lunch. We'll just take a half hour and we'll be back at 1:00.
- - -
(The jury leaves the courtroom.)
- - -
(A recess was taken from 12:28 p.m. to 1:12 p.m.)
- - -
THE COURT: You can be seated. Bring the jury in. The witness can resume the stand.
- - -
(The jury enters the courtroom.)
- - -
THE COURT: You may proceed.
MR. GAGE: Thank you, Your Honor.
- - -
CROSS-EXAMINATION
- - -
BY MR. GAGE:
Q Good afternoon, Dr. Klinge. How are you?

3493

A Good afternoon.
Q Good. My name is William Gage. I'm a lawyer and I represent Ethicon. And you and I have not had the pleasure to meet, so welcome to the United States.
A Thank you very much. It's a pleasure.
Q Now, sir, you've been paid about $100,000 for this case. Correct?
A Yes.
Q And when I did the conversion this morning, I went to the website and said how much is that equal to in Euros, and I think it's about 1.36 Euros.
Does that sound about right to you?
A Yes. It changes.
Q It changes daily, but if we had 100,000 -- if you got 100,000 bucks, and that's basically for the work that you did in 2012. Right? I mean, most of your work was in the year 2012 on this case?
A From my feeling, there has been a lot of work this year as well, but --
Q Let's stick mostly --
A It's for the entire time period here.
Q Let's stick with 2012.
If we got an exchange rate of about 1.36 or something like that, 100,000 US dollars is about

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136,000 Euros. Correct?
A Yes.
Q And you were kind enough to tell us at your deposition that you're actually employed by the University of Aachen; is that right?
A That is right.
Q I think you told us that -- you were kind enough to tell us at your deposition that your salary there is about 80,000 Euros a year?
A The salary is maybe more to 90,000 Euros a year. And the income of my family there, in 2010, for techs, was in about 160,000 Euros.
Q So the work for the University is somewhere around 90,000 Euros?
A Yes.
Q So the money that you would have gotten paid on this case would be one-and-a-third what you would get paid in a given year for your salary at the university. Right?
A I think you calculate it correctly.
Q Now, sir, just to make sure we got everything clear, you've never treated Ms. Gross. Correct?
A That is correct.
Q You never examined her?

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A That is correct.
Q And you've certainly not rendered any medical diagnosis specific to Ms. Gross. Correct?
A That is correct.
Q And you've not examined -- you know, you testified and you've talked about explants of mesh that you've examined. Correct?
A Yes.
Q And that's where mesh is taken out of somebody's body and you look at it, for example, under a microscope. Correct?
A That is correct.
Q And you've not examined any mesh explanted from Ms. Gross. Correct?
A That is correct.
Q And you have not examined any mesh that may still be inside Ms. Gross. Correct?
A That is correct.
Q Now, sir, in your expert report, you were kind enough to tell us that you've never performed surgery for repair of stress urinary incontinence. Correct?
A That is correct.
Q That's surgery in the pelvic floor, in the vagina. Correct?

3496

A You can say so.
Q And you've never performed surgery for the repair of pelvic organ prolapse. Correct?
A That is correct.
Q And that means you've never performed, for example, a native tissue repair, a colporrhaphy. Correct?
A That is correct.
Q And you certainly never performed a pelvic organ prolapse repair using a mesh. Correct?
A That is correct.
Q And obviously you've never used a Prolift. Correct?
A That is correct.
Q You've never used Gynemesh PS for a pelvic floor repair of any kind. Correct?
A That is correct.
Q And you've never placed a mesh with trocars. Correct?
A That is correct.
Q And you've never placed a mesh with cannulas. Correct?
A That is correct.
Q And you've never placed a mesh using the same tools as Prolift. Correct?

3497

A That is correct.
Q And, sir, you don't consider yourself an expert in the pelvic floor based upon the training you received in medical school. Correct?
A I'm not an expert in pelvic floor surgery in regards to the surgical procedure.
Q And I think you told us earlier, you're not an obstetrician or a gynecologist or a urologist or a urogynecologist. Correct?
A Yes.
Q You obviously completed no fellowships or residency or any other form of formal training in those fields. Correct?
A That is correct.
Q You've not studied the pelvic floor forces in a human. Correct?
A That is correct.
Q Sir, you stopped doing surgery. You told us that you had done hernia surgery, is that right, sir, for a period of time?
A Can you say it again?
Q Yes.
You told us earlier that you did hernia surgery for a period of time. Correct?
A That is correct.

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Q If I remember correctly, it's somewhere from around, what, the '90s up through about 2004, 2005?
A I started hernia surgery with the beginning of the residence. And this was in 1985. And stopped 2006.
Q 2006.
A In December.
Q So you hadn't been doing any hernia surgery since 2006. Correct?
A Yeah.
Q Now, sir, I want to talk to you a minute about polypropylene.
Polypropylene is what Prolift and Gynemesh PS are made of. Correct?
A That is correct.
Q Sir, you talked -- at the beginning of your direct examination, you talked about, you made a reference to the phrase "the history of hernia surgery." And I believe you said that you had been asked to lecture on the history of hernia surgery.
Do you recall mentioning that earlier this morning?
A I represent the history of mesh research of 20 years. So that was what I wanted to express.

Q And that's a subject, the history of hernia surgery and use of meshes in hernia surgery is a subject that you are familiar with?
A Yes.
Q Sir, I'm going to hand you an article, I'm sure you've probably seen it before, "Historical Development of Prosthetics in Hernia Surgery." And this is published in the Surgical Clinics of North America. Correct?
A That is correct.
Q Jamey, let's put up DLTB00647.
So we've got an article here, groin hernia surgery. And, Jamey, if you go down to the very bottom, you'll see that this is 1998. Correct, sir?
A That is correct.
Q And the title of it is, "The Historical Development of Prosthetics in Hernia Surgery."
And, sir, when we talk about prosthetics, we're talking about things like mesh. Correct?
A Yes.
Q Let's go over to .7, LT647.7. And let's get this paragraph, "Polypropylene Mesh," kind of front and center for us, Jamey. Thank you.
All right. So, sir, we see here --



actually, sir -- and, Jamey, you don't have to put this onto the screen, but, sir, you have got a copy of the article there. And you can flip through it if you wish.
But polypropylene mesh for use in the hernia space was not the first time a mesh was used in the hernia space. Correct?
A Please say it again?
Q Yes.
I mean, polypropylene mesh was not the first type of mesh used by physicians to cure hernias in surgical operations. Correct?
A That is correct.
Q In fact, doctors, really around the turn of the 19th century, looked at a variety of different substances and materials to repair hernias. Correct?
A That is correct.
Q They used things like stainless steel?
A Yes.
Q They tried to make meshes out of steel?
A Yes.
Q Fortisan?
A Steel is used in the sort of clinic as the major -- as the best suture material they found. So since 1944, they still used for this purpose sutures made of stainless steel and still are thinking that



this is the best. So there are different opinions about it and experiences, and it depends from the purpose of where you want to use it.
Q I mean, there are a lot of different opinions about what's being used. Right?
A Yeah.
Q Okay. So then we --
A It depends.
Q -- see polyvinyl sponge was once used or considered as a material for use in the hernia space. Right? You're familiar with that?
A Polyvinyl?
Q It's not on that particular page, sir. I'm just telling you -- here. I said you could look back in the article earlier. And you'll see that polyvinyl sponge was once used as a potential material in the repair of hernia surgeries.
Were you aware of that?
A I have to look through that. If you tell me where I can find it?
Q Look at 647.3.
A 647.3. Yeah.
Q Do you see that heading "Polyvinyl Sponge"?
A I know this, yes.
Q If you flip over on the next page, sir, you



see where nylon -- you're familiar with nylon. Correct?
A I know it, yeah.
Q And nylon was another substance that physicians and surgeons looked at as a possible way to repair hernias in people. Correct?
A Yes.
Q And then we have another substance called Silastic. Correct?
A Yes.
Q And that's a silicone-type product. Correct?
A Yes.
Q And then Teflon, you see that on the next page, that's another substance. You were aware of that?
A Yes.
Q And then carbon fiber, that was another substance that surgeons started looking at and saying, you know, what can we use. That was another one. You're aware of that. Correct?
A Yes.
Q And then we've got polyester, over on the next page, that was another substance that surgeons were looking for as a solution to the hernia space.

Correct?
A Yes.
Q And then we get to what we see on the page, after going through all that, on page 647.7, are you with me, sir?
A 647.7?
Q Yes. It's what's up on the screen.
A Uh-huh.
Q Do you see that?
A Yes.
Q It says, "Polypropylene mesh." And let's just do the first couple sentences there.
All right. And what we see, "Usher," he was one of the early pioneering surgeons; is that correct, sir?
A Yes.
Q "Usher introduced a new polyethylene plastic mesh called Marlex 50 in a series of experimental and early clinical papers in 1958 and 1959. This plastic mesh material had many obvious advantages over any type of metal mesh in use at the time."
Do you see that?
A Yes, I see it.
Q And polyethylene is not exactly the same



thing as polypropylene. Correct?
A That is correct, definitely.
Q Let's go over to the next page, LT647.8. And let's go down to the paragraph right here beginning "In 1962."
Okay. So we see here, "In 1962, Usher reported a collective review of 541 cases of hernia repair with Marlex mesh."
And that's the polyethylene that we just showed. Correct, sir?
A It is correct that you read it. Whether it is correct, I don't know, because sometimes they change to polypropylene. And I didn't know when it was.
Q That's exactly the point we're going to, sir.
A Yeah.
Q Look right here. Let's look right here. The -- let's do this whole paragraph right there, beginning with "The use of this."
"The use of this new polyethylene mesh prosthesis grew rapidly after its introduction, and by 1962, Adler" --
Again, sir, another physician. Correct?
A Uh-huh.
Q -- "Adler found in a survey of general



surgeons throughout the United States that 20 percent were using it for complicated hernia repair. In 1963, an improved version of Marlex was introduced by Usher based on a new knitted mesh of polypropylene monofilament fiber, used initially as a suture material, and this remains the prosthesis in use today, marketed by CR Bard of Billerica, Massachusetts as Marlex mesh."
Did I read that right?
A Yes.
Q So now it's 1963 and we've got a knitted mesh of polypropylene monofilament fibers. Correct?
A That is correct.
Q And if we talk about Prolift or we talk about Gynemesh PS, which is the mesh that goes into Prolift, we're talking about a polypropylene monofilament fiber. Correct?
A Yes.
Q Now, let's go down here. "In 1967." Right.
So we see here, in -- the article is telling us that, "In 1967, Collier and Griswald described the routine use of polypropylene mesh in inguinal hernia repairs and reported 212 consecutive repairs without a failure and without an infection."



Correct? Did I read that right?
A You read it right.
Q Now, let's go to 647.10. First few sentences of that paragraph, Jamey.
"The expansion of laparoscopic surgery," sir, that's where -- laparoscopic surgery in the hernia space is where you don't split somebody wide open in order to put a mesh in them. Right?
A Right.
Q You go in through the use of --
A Trocars.
Q -- trocars?
And you push the mesh down the trocar or down the hole, and then you look inside and you're operating inside the abdomen, it's kind of a blind procedure, but you still are able to see. Right?
A In some procedures, that is right.
Q So I just wanted the jury to understand what laparoscopic surgery is. And I think we've described it.
"The expansion of laparoscopic surgery showing an exponential growth as more and different procedures are being performed. Hernioplasty is now performed laparoscopically" --
And hernioplasty, that's fixing the hernia

with mesh. Correct?
A Hernioplasty?
Q Yes.
A Yes.
Q -- "is now performed laparoscopically with the major benefits reportedly being minimal patient discomfort and prompt return to full activities and employment."
Did I read that right?
A You read it right.
Q Now, let's go down a couple of paragraphs to the one beginning "Polypropylene."
"Polypropylene mesh has had an enormous impact on surgery over the past 35 years, and countless patients have had their lives extended or improved by its application to numerous surgical problems. It is quite clearly and justifiably the most popular prosthetic mesh available today for surgical implantation."
Did I read that correctly?
A Yes, you read it correctly.
Q Thank you. Jamey, you can take that down.
A Am I allowed to give a comment on this or not?
THE COURT: No. You have to just answer questions that are asked. And if your attorney wants



to ask something in follow-up, he can do that.
THE WITNESS: Thank you.
BY MR. GAGE:
Q Now, Doctor, I'm going to hand you an article, it's Defendant's Exhibit DLTB00170.
Sir, are you familiar with this article?
A No. I have to read it.
Q Sir, I'm not going to quiz you heavily on this article, so if you've just familiarized yourself with it, can we move forward with some questions?
A You see, it's difficult. You want to pose some questions whether you read it? I don't need to read it myself, because I can --
Q That's fair enough.
A If you say read it correctly, I can answer it.
Q Perfect.
A If you ask to the content, I have to read the entire text.
Q That's fair enough, sir.
We can see up here it's published in 1998. Correct?
A That is correct.
Q And it's the International Urogynecology Journal. Correct?
A That is correct.



Q Sir, that's not a journal that you have ever subscribed to. Correct?
A So far I know until now, not.
Q I'm sorry, did you say no?
A No.
Q No. All right.
Have you ever seen this article?
A No.
Q Anterior colporrhaphy, you understand what that is, don't you?
A Yes.
Q "Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles."
Do you know what a cystocele is, sir?
A Yes.
Q Jamey, let's get just the first couple of sentences of the abstract.
"This study assesses the use of Marlex mesh in conjunction with anterior colporrhaphy for the correction of cystocele with or without urinary stress incontinence. A retrospective review was carried out, 12 years of experience with 142 patients undergoing a modified anterior colporrhaphy reinforced with Marlex mesh."
Did I read that right, sir?



A Yes.
Q So let's go back up to the top. Let's look at the date on that article.
That's 1998. Correct?
A That is correct.
Q So if we've got 12 years experience with 142 patients using Marlex, we're looking at, what, 1998 minus 12 gets us back to the mid 1980s; is that right?
A What is the question, 1998 minus 12 years?
Q Yes. That gets us to what, 1986?
A '86 that means.
Q So we've got doctors implanting Marlex mesh for anterior colporrhaphy and for the treatment of cystoceles in the mid 1980s. Correct? According to this article?
A According to this article, he studied some of these patients, but I didn't see the follow-up, how many, how he did it. So we have to go in the details to see how reliable these results were that he reported them. So I have to read it.
Q Let's go to page 170.5. Let's go to the bottom paragraph where it says, "We believe."
And we see, "We believe that the modified anterior colporrhaphy reinforced with Marlex mesh is a safe procedure which can be performed in a patient with

symptomatic prolapse, even if it is their first operation."

Did I read that correctly, sir?

A You read it correctly.

Q Sir, let's go back to the first page of that article.

Go under "Materials and Methods." Just highlight that first sentence there.

We actually -- we've got "January 1977 to May 1992, 142 women underwent an extended anterior colporrhaphy reinforced with Marlex mesh."

So it's actually, instead of '86, it actually goes back to '97 -- I'm sorry, 1977. Right?

A You read it correctly, yeah.

Q Sir, I'm handing you another article. This is Defendant's Exhibit DLTB00325.

Have you ever seen this article, sir?

A I don't recall.

Q All right. And if we go up there to the top, the name of this journal is European Urology. And its publication date is 2000, but we see that it was submitted sometime in 1999. Correct?

A That is correct.

Q European Urology, that's not a -- that's not a journal you subscribe to, is it, sir?



A No.

Q And the title is "Tension-free vaginal mesh repair for anterior vaginal wall prolapse." Correct?

A That is correct.

Q And let's scroll up a little bit, Jamey.

All right. So under "Objectives," "We determined the efficacy of the use of a tension-free Prolene mesh to correct a grade III anterior vaginal wall prolapse recurrence." Correct?

A You read it correct.

Q And Prolene mesh was the precursor to Prolene Soft Mesh. Correct?

A From the timeline --

Q Yes.

A -- it is I think not correct, because Prolene is still sold, so it was a parallel development.

Q So I tell you what. Let me go to your expert report and let's get the history straight before we finish going through this article.

You told us in your expert report that Ethicon's use of polypropylene as a suture material dates back to the late 1960s. Right?

A May I have this expert report, sir, so I can take a look through it?

Q Sir, just to make it easier for you, I'll



go ahead and flip to the page that I'm going to talk to you about. Right there, page 9.

Sir, underneath your heading there in your expert report, "Ethicon's development of polypropylene mesh," you have there, "Ethicon's use of polypropylene as a suture material dates back to the late 1960s." Right?

A I see it.

Q When we talk about sutures, I'm from the southern part of the United States and we call them stitches.

A I can't comment on it.

Q But sutures, what we call stitches, are polypropylene threads that are used throughout the body to close wounds. Correct?

A If you say so, yeah.

Q Well, sir, I mean, I'm asking you.

That's what sutures are used for. Correct?

A Please again?

Q Yes.

Sutures are used -- they are polypropylene threads or filaments that are used to close wounds. Correct?

A Some wounds. Skin. So you would never suture bowels with a polypropylene suture. You would never do



so. So you have muscular damages you would treat, maybe some skin, but you will never -- some soft tissue --

Q Right.

A -- you will not use it for this.

Q And that's not -- I'm not trying to suggest that it's used --

A I think --

Q -- in every single place. That's not what I'm suggesting, sir.

I'm saying just simply that polypropylene has been used as a suture material in certain places in the body going back at least to the 1960s. Correct?

A No doubt about it.

Q And Prolene sutures, I'm reading now from your expert report, Prolene sutures were developed into a flat hernia mesh in 1975.

A Yep.

Q And they called that Prolene mesh?

A Yep.

Q Right? I mean, I'm just reading this right out of your report; is that correct?

A Yeah.

Q So then Ethicon then developed -- and this is on the next page of your report, Ethicon then

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developed Prolene Soft Mesh, which got launched in the year 2000. Right?
A Yes.
Q Okay. And then in 2002, Ethicon sold Prolene Soft Mesh as Gynemesh PS. Right?
A Yeah.
Q And then it was in '05 when Ethicon used the Gynemesh PS to go into the Prolift. Correct?
A That's correct.
Q So when we talk about Prolene mesh, and we talk about an article in 2000, right, we're talking about the Prolene mesh that Ethicon developed into a flat hernia mesh in 1975. Right?
A Please again?
Q Yes.
We got an article here, 2000. Correct?
A Yes.
Q And this Prolene mesh right here, this is not Gynemesh PS, is it?
A Obviously not.
Q Obviously not, because Gynemesh PS doesn't come out until 2002. Correct?
A Yes.
Q So this is what has sometimes been referred to as the heavier weight --

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A Yes.
Q -- Prolene mesh. Correct?
A Yes.
Q And the pores on the Prolene mesh are a lot smaller than the pores on the Gynemesh PS. Correct?
A Yes.
Q A good bit smaller. Correct?
A Yes.
Q And if we put them under your effective porosity testing, they would very likely fail the effective porosity testing. Correct?
A Correct.
Q Okay. All right. So let's get reoriented. Let's go back up to the top of the article. I just want to make sure we've got everything squared away.
European Urology, 2000, "Tension-free vaginal mesh repair for anterior vaginal wall prolapse."
All right. Let's now, let's go to the abstract. "We determined the efficacy of the use of a tension-free Prolene mesh," this is the heavyweight with the really small pores, "to correct a grade III anterior vaginal wall prolapse recurrence."
Correct? Did I read that right?
A You read it right.

3517

Q Under "Methods," "12 women (mean age 65.6 years) with stress urinary incontinence (SUI) four type II and one type III and bladder prolapse entered the study. After vaginal incision, a pretailored polypropylene mesh was fixed," and they go into the exact technique of how they do it.
So then we go down to "Results," and we see, "All patients were available for postoperative pelvic examination at three-month intervals for a mean follow-up of 20.5 months."
So what they are telling us there is, after putting the mesh in, the doctors then went in and did a pelvic examination of the women. Correct?
A Please, again?
Q Is that right?
A Please, again? I was still busy to read this.
Q Quite all right, sir. I'll be glad to rephrase it.
It says that, "All patients were available for postoperative pelvic examination at three-month intervals for a mean follow-up of 20.5 months."
My question is, that means that the women had pelvic examinations after having the mesh implanted. Correct? That's what postoperative means?
A That is correct, yes, yes.

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Q And then we see here, "No significant postoperative pain was reported by the patients." Correct?
A That is correct.
Q And under the "Conclusion" it says, "This study confirms that in patients with moderate cystocele a tension-free mesh to support a bladder base and neck effectively treats the cystocele. It is particularly recommended in the treatment of previous failure with traditional techniques and when the quality of suspending tissue is poor or defective"; is that right? Did I read that correctly?
A You did. Yeah, you read it correctly.
Q Now, sir, you mentioned earlier -- you can take that down.
You mentioned earlier, sir, that I think the amount of the mesh --
Ben, do you have the Prolift?
I'll ask the jury to remember the Prolift mesh.
THE COURT: You don't have it in the courtroom?
MR. GAGE: He said he has got it back at the war room.
THE COURT: Both sides refer to their rooms

as war rooms. Just so you know, it's equal.
MR. GAGE: Not that we're at war or anything.
THE COURT: Both plaintiffs and defendants call it that. We can proceed.
If you need the mesh, we can get it.
MR. GAGE: I don't, Judge. It's not that big of a deal.
THE COURT: All right. Go ahead.
MR. GAGE: The jury is going to get to see a good bit of it, so...
BY MR. GAGE:
Q Sir, you were talking about the amount of the polypropylene mesh in the implant.
Do you remember that? And I think you referenced four football fields?
A Yeah.
Q Hernia meshes are sometimes -- how big -- what's the biggest hernia mesh you ever implanted, sir? Maybe as big as that sheet of paper?
A This is Din A4. It is 30 to 20 --
Q Maybe even bigger than that?
A Bigger than this.
Q Bigger than that. All right.
So you've implanted meshes in people's



abdominal space that are bigger than that sheet of paper. Correct?
A But it's a completely different thing.
Q Totally different things?
A Yes.
Q You've got one in the pelvis and one in the abdomen. And I'm not trying to suggest they're one and the same, sir. I'm just trying to ask you a couple questions.
A Yep.
Q You've put that amount of polypropylene inside human bodies. Correct?
A Yes.
Q And if we were to take that mesh and we were to lay it end on end, it would go a lot longer than four football fields, wouldn't it?
A No. We have made at that time some calculations, and it was -- depending from the mesh you used, it was only 300 meters.
Q Only 300 meters?
A 300 meters, and -- yeah. So a little bit less. But it depends mainly from the textile structure. It doesn't make any sense to say how long. It is a huge amount of suture material.
Q And that's what I want to talk to you



about, sir.
Sometimes it's 300 meters and sometimes it may be 400 meters. Right?
A Yes.
Q Now, sir, when we talk about polypropylene, polypropylene mesh is currently the most utilized synthetic surgical material. Correct?
A You read it or you stated it?
Q I'm asking you whether it's a true statement, sir.
A I think it is correct.
Q Okay. Well, it was in your expert report. I was going to show it to you, but --
A I didn't learn it by heart, so...
Maybe we can read it.
Q As long as you agree to it, sir, I don't need to read it.
Polypropylene is favored for most mesh constructions. Correct?
A Yes. Favored, yeah. It's used for...
Q And polypropylene mesh is the most widely used material for hernia repair. Correct?
A Yes.
Q And polypropylene mesh is the most widely used material for pelvic floor repairs. Correct?



A Yes.
Q And 91 percent of all gynecological meshes sold in the United States are polypropylene. Correct?
A Yes.
Q And, sir, you would agree with me that polypropylene is appropriate for use in the pelvic floor if you have the right construction of the polypropylene. Correct?
A If you have the right construction, yes.
Q And mesh is an important option for patients in pelvic floor repair. Correct? You would agree with that?
A I can imagine that there are some patients, even in the pelvic floor, but I'm not a specialist for finding the best indication for a mesh in this area. I know from the abdominal wall that there is -- since 20 years, we have a lot of discussion, it is changing what is the best indication for these meshes, and there are areas where it's not an accepted indication to today.
Q All right. Now, sir, I want to go back for just a few minutes into your background and your history as a hernia surgeon. When I read your deposition, you know, obviously I was not the one coming over to Germany to take your deposition, but I've read your deposition. And I think you told us

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then that you had implanted meshes, many of which were polypropylene meshes, into something in the neighborhood of about 300 patients.

Does that sound about right?

A Yes.

Q Now, hernia surgeries are one -- I think I read it's the most commonly performed surgical procedure every year; is that right?

A For abdominal surgery, yeah. It's the most often performed procedure.

Q And in your deposition, I think you told us that 20 million meshes are implanted each year for hernia repair?

A The older figures are -- in US it's about 1 million, maybe worldwide maybe 2 million, and I was a little bit surprised. This came from a recent publication from around Kingsnorth, and there it was mentioned 20 million meshes, but they didn't specify for what purpose.

Q So a good portion of those are probably polypropylene. Correct?

A Yes.

Q So if we're getting 20 million people a year -- and let's just say, what, 10 million of them are polypropylene or have polypropylene in it, would

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that be a fair estimate, or would you say the number is higher than that?

A I cannot say. There aren't any data about it. But I would rely to the 2 million that are treated with meshes for abdominal wall. And, yeah, maybe there are 5 million, 6 million, but...

Q With polypropylene?

A With polypropylene.

Q And that's a year, per year. Right?

A That is -- would be the present status maybe.

Q So we're talking about a lot of people around the world?

A Yes. It's an important problem.

Q Tens of millions?

A Yes.

Q Potentially hundreds of millions?

A I wouldn't go so far.

Q Well, if you said 20 million a year --

A He said 20 million a year. And I told you that I think this is a -- but if you're looking to the Chinese, maybe we will get completely other, and India. So we are all small countries, even this one.

Q So long story short is, whether 20 million is right or 5 million is right, if you look over --

A It doesn't matter.

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Q It doesn't matter.

If you look over a 10, 15 or 20-year window of time, we're talking about certainly tens of millions of people on this planet are walking around with meshes in their body, and a large percentage of those meshes are either polypropylene or they contain polypropylene. Correct?

A Yes. But you are aware that you mix up a lot of different indications, materials and all this.

Q Correct. And we're going to get to some of that.

Now, one of the reasons that you and many, many other surgeons like you have used polypropylene meshes and other meshes is because, if you take a person who's got a hernia -- and, sir, I have to confess, before I got involved in this lawsuit, I was not an expert on hernias, but they can be significant and they can be serious. Correct?

A It was a complex question. Please, can you make it --

Q Yes.

Hernias can be --

A I have to translate it.

Q Hernias can be a serious condition. Correct?

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A Yes.

Q And surgeons sometimes try -- essentially it's an organ, maybe a piece of the abdomen, perhaps, that pushes through the abdominal wall?

A Yes.

Q And you need to be able to put that organ back so that the person doesn't have a more serious condition, such as the abdominal wall cutting off the blood flow to that particular organ. Correct?

A That can happen, yes.

Q And that can kill you. Correct?

A That can kill you, yes.

Q So one option the surgeons have, and at least in the hernia space, is to just simply use sutures, like we were talking about, stitches where I come from, where you stitch up, you open up the abdomen and you push the organs back in and then you can stitch it up. Correct?

A Yes.

Q And then another option is the use of a mesh. Correct?

A That is correct.

Q And one of the reasons that surgeons use the meshes in the hernia space is because of recurrence. Correct?

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A That is one aspect. However, we have -- since I'm in -- working in this field of abdominal wall hernia, every year we have several conferences with lots of discussions about when to do, what to do. And so...

Q Right.

A I think it is too simple to say, there is a hernia and you do it because of the recurrence. This is too short.

Q Well, one of the reasons -- well, reinforcement of tissues with mesh implants is definitely the treatment of choice due to reports of low recurrence rates.

Do you agree with that?

A Yeah.

Q Ease of use. Correct? Ease of use. Correct?

A Ease of use? The ease of use, yeah, yeah, yeah.

Q And low morbidity rates. Correct?

MR. ANDERSON: Objection, Your Honor.

May we approach, Your Honor?

THE COURT: Okay.

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(The following occurred at sidebar:)

MR. ANDERSON: Your Honor, we object. It's

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far beyond the scope. One of the things that I know that Mr. Mazie and Mr. Slater told you on Friday was that we were going to try to severely limit the areas of questioning that we went into. I cut out hours of things, and one of the things that I strictly tried to stay away from was getting into the history of hernia surgery, all of the various things about hernia surgery, the indications, the types of materials, because we could be here three days. And if I come back on redirect, we will, because I have mounds, mounds of hernia stuff that we can get into. And I didn't think we were going to do that. I thought we were going to talk about the Prolift.

I realize there is a little bit of crossover, and he's gone through a half hour of the history of that. But now we're getting into, there are parastomal hernia, there are esophageal hernia, there are all kinds of abdominal surgeries. We could go on with this forever.

And I thought that what we were trying to do is finish this today, if we could, and we never will like this, because he has gone so far down, and if he keeps going down this road, Your Honor, I have got to come back, because there are vast differences between hernia and pelvic organ prolapse. Vast differences.

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And it is an enormous load, because as he's already said, 50 years on that. Marlex alone we could go into forever.

You saw, Your Honor, that I specifically stayed on Prolift. I didn't talk about Ultrapro, I didn't talk about Marlex, I didn't talk about Prolene. I stayed away from it. But I could easily go there. And there's plenty of great stuff I could go into, but we will be here for a couple of days. And I have an opportunity, if he's going to keep going down this road, to go down that road. This is a huge area of medicine.

MR. GAGE: Your Honor, I have, I'm guessing five to seven more minutes based on his own experience, which happened -- unfortunately, happens to be only in the hernia space. And then I don't think -- I don't think we're going to be dealing specifically with hernia thereafter. I mean, obviously there's some things that relate to hernias, but that's not --

THE COURT: Well, I'm not going to limit you. I think that it's relevant and it's within the scope of the direct, even though it's a different branch of the direct, but it is in fact relevant to what he's testified to, which is generally whether this material is safe. I know he's indicated it's safe for

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one thing. Certainly the defense can bring out that he's used the material, that other people have used the material, that it's been around for a long time.

I personally would love to shorten the case as much as possible and avoid two days on the stand with this man, but I don't think that I can legitimately curtail the defense from going into some issues, and then you are going to have to make your call of what you need to go into.

MR. ANDERSON: Certainly.

- - -

(The sidebar ended.)

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BY MR. GAGE:

Q So, Doctor, we were talking about the surgeries that you were performing in the hernia space.

And I think we established that it was something in the neighborhood of 300 patients. Correct?

A Yeah.

Q And I know, I think from your deposition you indicated that you implanted Marlex mesh, one of the ones we looked at earlier, in some of your patients. Right?

A Yes, yes.

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Q And that's a polypropylene mesh. Correct?
A Yes.
Q And Atrium, that was the name of a mesh --
A Yes.
Q -- I think you implanted in some patients.
Is that a polypropylene mesh?
A Yes.
Q And then Prolene, that's an Ethicon mesh?
A Yes.
Q And it's made out of polypropylene.
Correct?
A Yes.
Q And you implanted that in some of your
patients?
A Yes.
Q And Ultrapro, that's a partially --
A A mixed.
Q It's a mix.
It's got polyglactin and it's also got
polypropylene in it. Correct?
A Yes.
Q I think you implanted that mesh in 150 of
your patients. Right?
A Yes.
Q And that's an Ethicon product. Right?

3532

A (Witness nods head.)
Q Now, sir --
A But, you know, it never -- it's used for
laparoscopic incisional hernia repair. There it's
forbidden to use any unprotected polypropylene mesh to
place it underneath.
So these are all open surgeries. It is a
failure in our field if you are using polypropylene
meshes in the abdominal cavity.
Q And, sir, in the 1980s and then in the
1990s and then all the way up to 2005 or '6 when you
stopped doing surgery --
A 2006.
Q -- 2006, you knew that all of these
surgical meshes that you were implanting carried
certain risks. Correct?
A Yes.
Q And that would include the risk of
infections?
A Yes.
Q And the risk of chronic pain?
A Yes.
Q And the risk of adhesions?
A Yes.
Q And the risk of mesh shrinkage?

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A Any operation carries some, yeah.
Q And you knew that there was a potential
risk for mesh erosion?
A Yes.
Q And, sir, I'm not trying to trick you, I'll
tell you I'm coming right out of your expert report on
this one, page 28.
You remember talking about foreign body
reaction and chronic inflammation on your direct exam
earlier this morning?
A Yes.
Q Remember we talked about that?
A Yeah.
Q Talked about fibrotic bridging, where the
scar tissue builds around the pores --
A Yes.
Q -- and causes problems for the patient?
A Yes.
Q It's a well-known fact and all the studies
indicate that all mesh products on the market today
cause an initial and chronic inflammatory tissue
response in the recipient after implantation. Correct?
A That's what we found out and published.
Q Every single one of them?
A Yes. But it doesn't say anything about the

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extent.
Q And, sir, when you were putting the meshes
in your patients, the 300 patients, you knew about all
of these risks, but you implanted them nonetheless
because you believed the benefits of the mesh
outweighed the risks. Correct?
A It's always a very careful decision whether to
make it or not. It depends from the patient, from the
age, from the location, from this analysis of the
individual risk balance that can be done. And as I
told you, that is a permanent discussion at our
conferences every year, ours.
Q Yes. And, sir, the reason that it's a
permanent discussion at all of your meetings and the
reason you've been discussing it since 1995 is because
no perfect mesh has been built yet, has it?
A It is well agreed by all of my colleagues that
there will be never a perfect mesh that fulfills all
these requirements. There will be no serious
researcher or surgeon who will claim that there will be
one ideal mesh for every purpose. It is not
imaginable.
Q Sir, let's -- I'm handing you an article
marked Defendant's Exhibit DLTB00045.
Have you looked at that, sir?

3535

A I don't recall exactly. Maybe.
Q And up here at the top, International Journal of Urology.
And that's 2012. Correct?
A Correct.
Q And, again, sir, this would be a journal that you do not subscribe to. Correct?
A Yes.
Q "Pelvic organ prolapse transvaginal repair by the Prolift system: Evaluation of efficacy and complications after 4.5 years of follow-up."
Did I read that right?
A Yes.
Q Let's go to page 45.5. And kind of pull that block out.
Sir, what we've got is kind of a summary of previous literature with regard to the Prolift. Correct?
A Yes, that's right.
Q And so what the author of this study is doing in 2012 is looking back in time at a number of other peer-reviewed publications published by other pelvic floor surgeons and doctors. Correct?
A That is correct.
Q And we've got the author over here. Right?

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And we've got the number of patients. Correct?
A That is correct.
Q So here we've got 75 in this one, 526, 254, 127, all the way down here to 323. Correct?
A Yes.
Q And they're all getting the Prolift except we got one Prolift+M. Correct?
A That is correct.
Q And then these are the different types of Prolifts. These are either the anterior, the posterior, or the total. Correct?
A Yep.
Q This is how far out they're coming back and checking in with the women. Right?
A Right.
Q So in this one, for example, the mean follow-up, kind of like the average, I know that average and the mean aren't exactly the same, but bottom line, average/mean means about the same thing. Right?
A Better would be the median.
Q I knew I was going to get that. The median, 54 months.
But essentially, bottom line is they're going in -- 54 months is what?

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A It gives an estimate that they -- it's not two months, it's longer.
Q It's not two months. They go in something like four-and-a-half years after they got the Prolift, and then they looked at cure rate and mesh exposure; is that right?
A Yep.
Q So when we look at the cure rate, we see 81.5. And when we talk about anatomical cure rate, we're talking about fixing the prolapse. Correct? Repairing the prolapse?
A I'm aware that there is a big discussion, what is the best readout, is it the anatomical, is it functional, is it -- yeah.
MR. ANDERSON: Objection, Your Honor. May we approach?
- - -
(The following occurred at sidebar:)
MR. ANDERSON: Judge, he didn't go into any of this literature on his direct. He's only a materials expert. He hasn't got into success rates, recurrence rates.
THE COURT: I think this is beyond his expertise, as far as just talking about how often it cures the problem. He's indicated he is not a surgeon

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who ever has done this. He doesn't prescribe to these.
MR. GAGE: There's a very specific point that I want to go to.
THE COURT: What's that?
MR. GAGE: That is that the Prolift+M, which has the larger pores than does Prolift, has a lower cure rate and a mesh exposure rate that is basically the same.
MR. MAZIE: He hasn't gone into Prolift+M.
MR. ANDERSON: We specifically didn't go into Prolift+M. Plus he doesn't subscribe to these. He's not a urogyn. You did a great job of saying what he doesn't do and what he hasn't reviewed. These would be great for urogynecologists. You had your chance with Weber would be my position, respectfully.
This guy is a biomaterials science researcher, abdominal surgery. You went into it, you said you have five to seven more minutes. If you want to start to get into studies, clinical studies, RCTs and comparative trials, that's already been gone into in this case.
THE COURT: Well, if you want to ask him if the Prolift+M has larger pores, you can certainly establish that through this witness. But the success rate as far as -- and he's indicated he doesn't know

whether we're talking functional success rate, anatomical success rate. It's not within his expertise. You can ask him if there's larger pores. And then you can bring the study up with one of your witnesses. I'm sure you will.

MR. ANDERSON: Thank you, Your Honor.

- - -

(The sidebar ended.)

- - -

BY MR. GAGE:

Q Jamey, let's put that back up.

Now, sir, the point of putting this up here is to go to Prolift+M.

That is actually the Ultrapro material. Correct?

A Yes, that is correct.

Q And the Prolift+M has larger pores than the Prolift. Correct? Or the Ultrapro has the larger pores than the Gynemesh PS. Is that fair to say?

A This is not true with strain. Without strain, this is true. But if you apply some strain, it is not true.

Q What about without strain?

A Without strain, yes.

Q It's got larger pores?



A Larger pores.

Q You can take that down.

Let's put up Plaintiffs' Exhibit -- or PLT0261.

Sir, you remember, I think you talked about this article this morning. Do you remember that?

A Yes.

Q And I think this was the article where you indicated it was -- let's just look at the title here. "Shrinking of polypropylene mesh in vivo: An experimental study in dogs." Right?

A That is right.

Q That's one of your studies, Uwe Klinge. Correct?

A Yes.

Q I think we came down here, you mentioned something about meshes that contain a lot of polypropylene shrink to about 30 to 50 percent of their original size. Correct?

A Yes.

Q Now, sir, this study, if I understand it, did not involve Gynemesh PS or Prolift. Correct?

A That is correct.

Q You take that down, and let's put up Defendant's Exhibit 372.



Sir, I'm handing you a copy of Defendant's Exhibit 372. Give you just a second to look that over.

That's an internal e-mail from Ethicon. Correct?

A It appears to be so, yes.

Q And you looked at a lot of internal documents. Correct?

A Yes.

Q Correct?

A Yes.

Q And was this one of the ones that you looked at?

A No.

Q I'm sorry?

A No.

Q You never saw this document?

A The first page, not. I'm --

Q I'm sorry, go ahead and take your time to read it, and then I'm going to ask you, have you seen this document before.

A Yes.

Q Sir, I'm not going to quiz you on the details, just kind of big picture.

Do you remember --

A No, I have never seen it.



Q You've never seen it?

A No.

Q So I'm not going to read the whole thing to you, sir, because it's pretty lengthy, but, Jamey, let's start here in the middle where it's from Cosson. Yeah, right there. All right.

So you know Dr. Cosson or you're familiar with him from looking at your documents. Correct?

A Yes.

Q He was one of the doctors I think that was in on the ground floor of Prolift. Is that fair to say?

A Yes.

Q And I think he was -- I think he was involved in the TVM studies. Correct?

A Yes.

Q So he was there from the very beginning. Correct?

A If you -- yeah.

Q So here he is e-mailing somebody at ETHUS. And you understand that to be Ethicon US. Right?

A Yes, uh-huh.

Q And the date is February 25, 2004. Correct?

A Yes.
Q That is almost one year before Prolift goes on the market. Correct?
A Yes.
Q And he says, "Joshua." And just so we get things clear, I think he's from France. Right? Dr. Cosson?
A I think so as well, yeah.
Q And you're from Germany, and sometimes e-mails don't get quite typed the way that people that speak English read it. So you may see some stuff in here that doesn't quite make sense, but he says, "I join you the answers. I apologize for the delay. Sincerely yours, Michel." Right?
A You read it right.
Q So let's go to the next page. And let's look at question number 7. "Is it critical that mesh straps lay flat in channel or is it ok to be rolled-up?" And Dr. Cosson says, "If the mesh is in place, there is no problem for a roll-up."
Do you see that?
A Yes. This is evidence to class level 5, evidence level 5. It's just expert, meaning no data.
Q You can take that down.
Now, sir, we talked about -- you talked



earlier about fibrotic bridging?
A Yes.
Q Where things build around the scar or build around the mesh and form a scar plate. Right?
A Filling out the pores.
Q Filling out the pores.
And that's not a good thing --
A No.
Q -- in your opinion?
A Yeah. In most of the indications, if you made a replacement of a knee ligament, maybe it's different. It depends.
Q So on this subject, I'm going to hand you Defendant's Exhibit DLTB00266.
Do you see that?
A Yes.
Q That is something -- that is a document you have seen before. Correct?
A Yes, I have seen it.
Q And you've seen it because you wrote it. Right?
A Yes.
Q All right. So the title of it is, "The lightweight and large porous mesh concept for hernia repair." Correct?



A Yes.
Q And I think you talked about Dr. Klosterhalfen earlier?
A Yes.
Q And you and he are co-authors on this document. Correct?
A Yes.
Q Let's go to the bottom so we can get a date on it.
And this is 2005. Correct?
A Yes.
Q And, sir, let's flip over, it's page 105 of the article, the reference number is Defendant's LT266.3.
Do you see that?
A Yes.
Q And there's a header there called "Integration into the abdominal wall biocompatibility." Correct?
A That is correct.
Q When we talk about biocompatibility, I know you probably have a lot more technical definition than I can articulate, but as I understand it, it is basically how well is the mesh going to do inside the human body?



A That is maybe your definition.
Q Well, that's what I said. That's just kind of a big picture definition.
Biocompatibility is how the body reacts to the mesh once it's implanted?
A It includes two parts. First is the function, so you use this term to describe whether it has a good biocompatibility or a bad. Therefore, we use this term. And one aspect is always the function, whether it's able to preserve to restitute the function, and the second is whether this is combined with added tissue damage to this.
Q Okay.
A And, therefore, it depends very much from the way you use it. You cannot say that something has a biocompatibility -- a high biocompatibility for any purpose. That would be the same as if you are looking for the ideal mesh for every purpose.
Q But can we agree that biocompatibility -- we want our meshes to be biocompatible?
A I hope so.
Q Right. I mean, biocompatibility, when we talk about having good biocompatibility, that's a good thing for the patient. Correct?
A Yes, if --

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Q And when we talk about bad biocompatibility, that's a bad thing for the patient. Correct?
A Yes.
Q Now, let's go down to the bottom of the beginning of this second paragraph. "Today, it is not fully clear why inert and nonimmunogenic materials induce this type of inflammation known as foreign body reaction (FBR)."
And, sir, I think you talked about foreign body reaction when you were up here, when Mr. Anderson was asking you questions?
A Yes.
Q And foreign body reaction and biocompatibility are related notions?
A It has to be considered, of course.
Q But, I mean, in other words, foreign body reaction and biocompatibility are more or less the same thing?
A No, no, definitely not. Because a foreign body reaction, you always have -- you always -- you cannot -- there is hardly any situation where you don't have the macrophages around the foreign body.
Q That's with every mesh?
A Yes. Therefore, a foreign body reaction, you always have it.

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Q Correct.
A But the extent of foreign body reaction, this is important for the function later on. And, therefore, we are coming back to the design for the function for the purpose where to place it.
Q Right. And what I meant --
A But foreign body is a completely separate thing.
Q What I meant I think -- you have a scientific mind and I don't. I didn't mean it quite at that level. I think what my --
A Therefore, I'm sitting here and you're standing there.
Q That's exactly right.
A Yes.
Q What I mean is that biocompatibility and foreign body reaction both, at a very high level, deal with concepts of the mesh once it's inside the body. Correct?
A I didn't understand this question clearly. There is -- as I told you --
Q I tell you what, let's keep going. I think we'll be able to solve our problem as we keep reading through this document.
A I'm sure. It's not helpful to stick to this.

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Q Okay. "So today it is not fully clear why inert and nonimmunogenic materials induce this type of inflammation known as foreign body reaction (FBR)."
That's what you just discussed, right, FBR?
A We discussed foreign body reaction. This sentence means that we don't know at a genetic and molecular level what exactly happens. You always saw these macrophages, but what goes in detail there, we know a lot of molecules today, so there are some -- there has to be done a lot of research to understand this better. This is what this sentence is expressing.
Q So let's go to page 111 of the article, which is Defendant's Literature 266.9. And let's highlight the first couple of sentences -- or let's go up to this fibrotic bridging section.
Sir, I believe you talked briefly about fibrotic bridging. Do you recall that?
A What?
Q I believe you talked earlier about --
A Yes.
Q -- fibrotic bridging?
A Yeah, sorry. I read it already.
Q Oh, that's fine.
So we see up here, "Fibrotic bridging is a phenomenon which is, in the author's opinion" -- and

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that's you. Correct? You and others?
A Yes.
Q -- "closely associated with the occurrence of shrinkage."
We've talked about shrinkage, haven't we?
A Yes.
Q "Moreover, the incidence of bridging is unrelated to the textile structure of the mesh."
That's what that sentence says. Correct?
A Yeah.
Q And then it says, "Bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half of the pore size of the mesh." Correct?
A Yes.
Q Now, Jamey, if we could, let's pull out and go to the next column on the same page under the heading --
A The next sentence would be helpful.
Q No, no, no. Down here to "Chronic pain." There we go.
All right. So -- and, sir, you talked about -- I think you talked about pain earlier this morning. Correct?
A Yes.

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Q And chronic pain means pain that keeps going. Right?
A Yes.
Q It doesn't go away?
A Yes.
Q "In contrast to neuropathy-related complaints after intraoperative damage of nerve fibers with pain immediately after surgery," and I want to pause there before we finish the sentence.
What we're talking about there, sir, is during the operation, the patient has some nerve fibers that are damaged, and that leads to pain after -- right after the surgery. Right?
A It can, yeah.
Q So in contrast to that kind of pain, the onset of chronic pain as a consequence of the fibrotic -- of the FBR is typically more than one year after hernia repair?
A In the groin.
Q That's what you've got right there. Correct?
A Uh-huh.
Q Sir, we talked about -- I should say you talked about. We talked about that -- we talked about some of the testing on the mesh. Do you remember that?

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A Yes.
Q And we talked about uniaxial and multiaxial. Do you recall that?
A Yes.
Q I'm going to hand you an article here, it's Defense or DLTB00139.
Sir, you've seen this article before. Correct?
A Yeah, I've seen it.
Q This article comes out in 2005. Correct? So it's 2005. Correct?
A Yeah, that is correct.
Q And these are a number of surgeons in Belgium out of the department of obstetrics and gynecology. Correct?
A That is correct.
Q So let's go over -- let's go to the next page.
Do you see that header down there, "Synthetic implants"?
A Yes.
Q All right. So "Polypropylene mesh became the most commonly used synthetic prosthesis. Simple synthetic filaments, yarns, are used to manufacture these implants. There is, however, considerable

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variation of fiber diameter, knotting or weave configuration and size of pore and/or interstices. Meshes can be made from knitted single fiber-filaments," which they called monofilament materials, "or they can be braided with monofilament yarns, further woven as multifilament fibers in different ways and pore sizes."
Now, sir, Gynemesh PS, going back to Gynemesh PS, is it a knitted fabric?
A I think it would be named as a knitted fabric, yeah.
Q And it's a monofilament?
A The term or the naming of monofilament has its limitation. The filament that is used is a monofilament instead of a multifilament. But at the knots, it is a multifilament or oligiofilament structure because that means that the filaments are coming close together.
Q So now let's go up to Figure 1. And let's just start here where it says, "Knitted fabrics." It says, "Knitted fabrics have a more open structure than woven. The knit construction allows the mesh to be stretched in both directions to accommodate and reinforce tissue defects. Fabric is produced in such fashion as to interconnect each filament yarn and

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provide bidirectional elasticity, while allowing the mesh to be cut to any shape without loosening yarns."
Did I read that correctly, sir?
A You read it correctly, yeah.
Q Thank you.
MR. GAGE: All right. Judge, I'm about to do a big shift.
THE COURT: Let's take a break.
MR. GAGE: Okay.
THE COURT: We'll take a 10- or 15-minute break.
- - -
(The jury leaves the courtroom.)
- - -
(A recess was taken from 2:36 p.m. to 2:58 p.m.)
- - -
THE COURT: You can bring the jury in.
- - -
(The jury enters the courtroom.)
- - -
THE COURT: You can be seated and you can continue, Mr. Gage.
MR. GAGE: Thank you, Your Honor.
BY MR. GAGE:

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Q Dr. Klinge, I'm handing you a copy of the -- this is your effective porosity article. The jury has seen it a number of times. Jamey, let's put it up. I've got it as PLT0346.

Dr. Klinge, the jury has heard Dr. Muhl.

Have you read Dr. Muhl's testimony?

A Yes.

Q So you know what he's already told the jury?

A This testimony here? No, I didn't get it.

Q Well, I'm not going to cover every single aspect of the testing, because we covered a lot of that with Dr. Muhl, so I didn't want you to feel like I was leaving out some portions and asking you only about others, but we covered a good bit of it. I want to just kind of hit the stuff that --

A I'm happy with it.

Q That's good.

So bottom line is -- well, the first thing I want to establish is you didn't publish this until 2007. Right?

A Yes.

Q And that's when the results of this new objective measurement, I mean, that's when it went out. Right? 2007?

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A Yes.

Q And you're one of the authors. Right? Along with Dr. Muhl?

A Yes.

Q Now, let's go to -- it's one, two, three, four -- it's the fifth page, Jamey. And there's Table 1 at the bottom of that page.

Dr. Klinge, you remember Table 1? Do you see that?

A Yes, I see it.

Q Now, you tested four meshes, Optilene, Sofradim, TiMesh and DynaMesh. Right?

A Yes.

Q Just so the jury follows where we're going, this is the testing you did in 2007, not the testing you did of Prolift in 2012. Right?

A Yes.

Q Now, Optilene, if we go over here on the table, had 0 percent effective porosity. Correct?

A Yes.

Q And I think you said that's because none of the pores were larger than 1 millimeter. Right?

A Yes.

Q And we've talked a lot about 1 millimeter and we've also talked about 75 microns. And the jury

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is going to probably see some things that talk about 1,000 microns. So let's get everybody accustomed to what we're talking about.

As I understand it, 1 millimeter is how many microns?

A 1,000.

Q So 1 millimeter is 1,000 microns?

A Yes.

Q And so when you did the testing here, you did the same thing that you did with the Prolift testing -- to the Prolift mesh in 2012. Right?

A Yes.

Q I mean, it's the same testing. Right?

A Yes.

Q Same testing method?

A Yeah.

Q And you looked at the mesh. And using cameras and a computer, you counted the number of pore spaces that were larger than 1 millimeter. Correct?

A Yes.

Q And if the mesh doesn't have a pore size that's larger than 1 millimeter, it's got 0 percent effective porosity. Correct?

A Yes.

Q So Sofradim was another mesh, and it had a

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29 percent effective porosity. Right?

A Yes.

Q And TiMesh light had 0 percent effective porosity?

A Yes.

Q And DynaMesh polypropylene light had 42 percent. Correct?

A Yes.

Q So DynaMesh basically won the kind of best in show, right, at least for purposes of your testing. Correct?

A I would object to the term "won."

Q Fair enough. It had the best effective porosity of any of the four meshes that you tested?

A Yes.

Q Now, you also tested a DynaMesh mesh in 2012 when you tested the Prolift mesh. Correct?

A Yes.

Q And it was a pelvic floor mesh?

A Yes.

Q It's made of a different material called PVDF. Correct?

A Yes.

Q If I remember the wording from your expert report, you said that the DynaMesh mesh had excellent

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porosity -- I'm sorry, excellent effective porosity. Correct?
A It has a higher, because it has a higher structural stability, yes.
Q So when we ran the 2012 test, we had a DynaMesh mesh and we had one made by Ethicon. And the DynaMesh test or the DynaMesh mesh in 2012 had the higher effective porosity. Correct?
A Yes.
Q Now, DynaMesh is manufactured by a company called FEG. Right?
A Yes.
Q And they're in Aachen. Right?
A Yes.
Q They're a German mesh maker?
A And they made the Vypro for Ethicon at that time.
Q And I think you're a paid consultant to FEG?
A Yes.
Q And you and Dr. Muhl do a lot of work with them, with FEG?
A We have some granted studies with them.
Q And you've been studying their mesh for how many years? If we go back to '07, you've been doing their mesh for at least five years. Right? You've

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been working with them for the last five years. Right?
A They have been employed for the first time in 1994 to produce the Vypro with us, because Ethicon at that time, they needed someone from the Institute for Textile Engineering in Aachen. And so these guys, they give the structure of the Vypro at that time. And since then we are working on finding best solutions for meshes.
Q I understand that and --
A So I'm working since 1994 with these guys.
Q So since '94 you've been working with FEG?
A Yes.
Q And you worked with Ethicon up until about, what, '05 as a consultant?
A 2005.
Q 2005. And then you were no longer a consultant for Ethicon. Correct?
A Yes.
Q But did you stay as a consultant for FEG after 2005?
A Yeah. We had a lot of -- or several granted projects together.
Q As we sit here today, you are a paid consultant for FEG. Correct?
A Yes.

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Q You talked about patents earlier. Do you remember that?
A Yes.
Q Those are mesh patents. Right?
A Yes.
Q Did you assign those patents to FEG?
A I didn't get the content of the sentence?
Q Did you assign those patents to FEG?
A With the FEG. They were patents from the FEG where I was a contributor to this.
Q So you invented meshes. Correct? Or helped to invent meshes. Correct?
A Yes, yes.
Q And then you got a patent on that mesh. Correct?
A I was mentioned on this patent, yes.
Q Because you helped to invent it. Correct?
A Yes.
Q And then FEG, did they buy the patent from you?
A No.
Q You gave them the patent?
A No. They claimed this patent for these meshes, and they made --
Q Listed your name?

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A And they listed my name as a contributor. This was a procedure not done by every company, I have to admit.
Q And what year did you start as a paid consultant for FEG? Was it '94 or did they start paying you sometime after '94?
A No. It was '98 maybe, '99.
Q So the last 14, 15 years you've been working for them?
A As I told you, together with Ethicon, we have been working with the FEG starting in 1994.
Q But the Ethicon work stopped in '05. Right? Your Ethicon worked stopped in '05. Right?
A Yes. And the Ethicon work with the FEG stopped I think in 1997, 1998.
Q For example, if we go to the DynaMesh website, the FEG website, we're going to find a picture of you on the website. Right?
A I haven't seen it myself, but --
Q You haven't seen the picture of the newspaper interview with you on the website?
A I know there has been a -- we got an award to make a grant for visible meshes, and there has been a report in the newspaper and maybe they placed it on the website, but I didn't control their website. But it

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was an excellent project.
Q So we got this testing going on. And I looked in the article, and it's not that big of a deal, but you didn't -- there's no mention in the article that you're a paid consultant for FEG or for DynaMesh. Right?
A That is right. Maybe. So I have to check whether there is any acknowledgment to any others.
Q And, sir, let me hand you another study. I'm sure you've probably seen it. It's an article called "Comparison of a lightweight polypropylene mesh Optilene LP."
And, sir, what I'm going to do up here, just so you and I are on the same page, I'm going to use the letters -- that's an E, it doesn't quite look like it -- EP for effective porosity. That's what I mean by EP.
A Yeah.
Q Okay. So Jamey, take down what you got on the screen and let's put up, it's DLTB00863.
And here we see, sir, a comparison of a lightweight polypropylene mesh Optilene LP, and they're looking at another mesh made out of a different material called PTFE. Correct?
A Yep.

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Q And this is published in 2012?
A Yes.
Q In the Archives of Surgery?
A Yes.
Q And what we've got here are a number of individuals, a number of physicians from the Department of Surgery and Center of Minimally Invasive Surgery. Do you see that? It's down here at the bottom. Let's scroll up. Right there.
See, Department of Surgery and Center for Minimally Invasive Surgery; is that right? And these are doctors in Berlin. Right?
A In Berlin, yeah.
Q So let's go back up to the abstract. And we see the purpose of the study, they say on the first sentence, "The use of a mesh with good biocompatibility properties" --
Biocompatibility, that's what we talked about earlier. Right?
A Yes.
Q -- "is of decisive importance for the avoidance of recurrences and chronic pain in endoscopic hernia repair surgery."
And then we go a little further down to "Methods," and we see that, "20 domestic pigs were

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implanted with either a lightweight large pore polypropylene mesh, in this case Optilene LP, or this other medium weight PTFE mesh." Correct, sir?
A Yes.
Q And we see over on, I think it's two pages over, Jamey, if you could, we see up in the top right, we see, "HE staining."
And that's once you get -- what they do is they put these meshes in pigs. Right?
A Yes.
Q And then they let the pigs live for a certain number of days. Right?
A Yeah.
Q And then, in this case, it was 94 days?
A Yeah.
Q And then the pigs are sacrificed. Correct?
A Uh-huh.
Q And then they take the mesh out, and then they look at the mesh under microscopes. Correct, sir?
A Yes.
Q And that's the sort of stuff you do? I mean, you put meshes in animals and then later examine them under microscopes. Correct?
A Yes.
Q So we're at page 285. And HE staining,

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what's that, sir? Is that where you're staining the slide so you can see them better?
A Yes. It marks the -- some cell components, the nucleus, and so you can see a little bit better the collagens or the scar.
Q So it says here, "HE staining showed good integration of both meshes with only minor inflammatory reaction and no bridging scar tissue between the filaments"; is that right?
A Yes.
Q Then if we flip over to -- let's go to the conclusion, Jamey, at the end of the article.
First paragraph of that conclusion. It says, "In our experimental examinations, Optilene LP and INFINIT showed comparable biocompatibility in terms of chronic inflammatory reaction. The good tissue integration and biocompatibility coupled with the good adhesion characteristics on the tissue make the Optilene and the INFINIT meshes suitable for implantation in hernia repair surgery."
Did I read that correctly?
A Yes.
Q You can take that down.
All right, sir.
Jamey, can you put back up Dr. Klinge's

2007 article? Put up that Table 1. Do you remember? It's PLT0346. There you go.

So now we're going to move on. We're going to skip over Sofradim and we're going to go to TiMesh. All right?

A Yeah.

Q And, again, TiMesh had 0 percent effective porosity. Correct?

A Uh-huh.

Q Sir, I'm going to hand you an article called -- well, let me just hand you that.

Sir, you're familiar with this article. Correct?

A Yes.

Q I'm sorry, you can take this one down, Jamey, the one that you've got up, and let's put up DLTB00864. All right?

And, Doctor, that's the one you're holding in your hands. Correct?

A Yes.

Q And you're familiar with this article? This is an article that you are one of the authors on. Correct?

A Yes.

Q And if we come down here, go up, Jamey.



Right there. That's good. Kind of in the middle of this sentence, over in the abstract it says, "In Sprague-Dawley rats, mesh samples were placed in a subcutaneous position. And then 56, 84 and 182 days after mesh implantation, three animals from each group were sacrificed for morphological observations." Right?

A Yes.

Q And that Sprague-Dawley rats are just a type of rat that you use in some of your experiments. Correct?

A Yes.

Q So in the prior study, we saw pigs. And in this study, we see rats. Correct?

A Yes.

Q So after getting the TiMesh implanted in them after 56, then 84 and then 182 days, the animals were sacrificed and you took the meshes out and you examined them under microscopes, like the guys did with the Optilene in the pigs. Right?

A Yes.

Q So let's go over, Jamey, to 864.4 and that paragraph beginning, "Overall."

We see that, "Overall, both mesh materials showed a moderate foreign body reaction with a small



amount of connective tissue formation indicating a good biocompatibility"; is that right? Did I read that correctly?

A Yes.

Q Sir, I'm going to hand you another article, and this one -- Jamey, this one is DLTB00865.

Sir, have you ever seen this article?

A I've seen it.

Q And the title on this one is "Randomized clinical trial of laparoscopic hernia repair comparing titanium-coated lightweight mesh and medium-weight composite mesh." Correct?

A Yes.

Q And this is dated 2012. Correct?

A Yes.

Q TiMesh, the reason it's got "Ti" in front of its name is because it's a got a little bit of titanium that covers the mesh. Correct?

A Yeah.

Q So let's go up, Jamey. Let's look at "Methods." "Randomized controlled single-center clinical trial was designed using the basic principle of one unit, one surgeon, one technique and two meshes, a lightweight titanium coated mesh," and this is TiMesh, sir, we'll see it later in the article, "and a



medium-weight collagen-polyester composite mesh. The primary endpoints were pain and recurrence. The secondary endpoints were morbidity and patient outcomes."

And, sir, unlike the two that we looked at earlier, this is actually in humans. Right?

A Yes.

Q This isn't an animal study. Correct?

A Yes.

Q And we see down here over on the "Conclusions," and let's just block that paragraph on the "Conclusions."

"The lightweight titanium covered polypropylene mesh was associated with less postoperative pain in the short term, lower analgesic consumption and a quicker return to everyday activities than the Parietex composite medium-weight mesh."

And the recurrence rates at two years were no different; is that right? Did I read that correctly?

A You read it correctly.

Q Then the next page -- you can take that down. Jamey, the next page -- put that same article back up. Let's just go to the second page, near the bottom.

3571

And we can see here, sir, that that's the TiMesh light that they were looking at. Right?

All right. You can take that down.

Sir, I think I've already handed you this article, but I've got another copy if you need it. This is Defendant's Exhibit DLTB00266. We've already referred to that once before, but feel free to use this document.

And the jury has already seen this document or this article. This is your article. Correct, sir?

A Yes.

Q So let's go over to 266.11. And under "TiMesh light and extra light," we read down here, this is where you're talking about TiMesh light. Correct, sir? And TiMesh extra light?

A Yes.

Q And "Both" -- it says here, "Both mesh modifications were announced as a revolution on the mesh market and have the best biocompatibility possible. Indeed, the titanium modified meshes exhibit a significantly increased biocompatibility compared with conventional heavyweight small porous meshes." Correct? Did I read that right?

A Yes.

Q Sir, we're now going to move to Gynemesh

3572

and Prolift, which you tested not in 2007 but in 2012. Correct?

A Yeah.

Q Sir, I'm going to hand you Defendant's Exhibit 2257.46. Sir, I've only got one copy, so I'm going to let you look at it, then I might take it back from you for just a second.

A That's fine.

Q Just take a look at that.

After you've had a chance, is that one of the documents that you were sent?

A Yeah, I have seen it.

Q That's an Ethicon document; is that right?

A Yes.

Q And, sir, I've got a sticky there.

Do you see the sticky on that page?

A Sticky?

Q Yeah. That's what we got up on the screen. Right?

A Yeah, yeah.

Q And it says here, "Pore size of Gynecare Gynemesh PS"; is that correct?

A Yeah.

Q And then down here we've got 2530, and that's kind of a funky looking UM. Right?

3573

A Yes.

Q And in scientific language, is that the symbol for microns?

A Yes.

Q So if you -- as I understand this, what this is saying is that the distance from this spot right here running through this spot right here is 2,530 microns. Correct?

A That's what it says, yep.

Q I'm sorry?

A Yeah.

Q Remember we talked earlier about how to compare millimeters to microns, we said that 1,000 microns is equal to 1 millimeter. Correct?

A Yes.

Q So if assuming the math and the measurements here are correct, the distance from this spot right here to this spot right here would be 2,530 microns. Correct?

A That is correct.

Q And on this -- and then up here -- this is the width, and I guess they call that the height. Correct?

A You can call it --

Q You can call it whatever you want to call

3574

it, but at least the distance here is 1,750 microns. Correct?

A Yes.

Q And then here it says, "Macroporous."

I think you talked earlier about microporous and macroporous. Correct?

A Yes.

Q And microporous means the mesh has a small pore; is that correct? I know that you can get --

A You can use this expression if you made a reference that this is the definition of Amid from 1997, and then this is the type of macroporous.

Q So under the Amid classification that you talked about, which was I guess Dr. Amid; is that right?

A Prof. Amid. Prof. Amid.

Q He created a classification of meshes and published on it back in 1997; is that right?

A In the first issue of Hernia, yes.

Q In the first issue of Hernia.

And under his definition, this would be -- the Gynecare Gynemesh PS would be defined as macroporous because it had pores at least 75 microns. Right?

A Yes.

3575

Q You can take that down.
Sir, I'm handing you what's been marked as DLTB00104.
And, sir, you know this article because you wrote it. Correct?
A Yes.
Q And this is published in Hernia in 2004. Correct?
A Yes.
Q And the title is "Polypropylene in the intra-abdominal position: Influence of pore size and surface area." Correct?
A Yes.
Q Jamey, let's go to the next page, 104.2.
And here, sir, under number 2, we see "Group II." Correct?
A Yes.
Q In other words, I think what was going on here, sir, is you were looking at several different polypropylene meshes. Correct?
A That is correct.
Q That's what you were doing in this study?
A Very, very huge lot of pores. We wanted to have this polypropylene and to look what happens within the abdominal cavity at this.

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Q So you looked at -- three different polypropylene meshes are investigated. Correct?
A Yes.
Q And they all differed in weight, filaments and pore size. Correct?
A Yes.
Q And there's Group I, and they were small porous with pore sizes of .6 millimeter.
And if it's .6 millimeter, that would be 600 microns. Correct?
A Yes.
Q Heavyweight mesh for monofilament polypropylene. And then we go to Group II. And it's PP 2.5.
And that means the medium porous, the pore size is 2.5 millimeters. Correct?
A Yes. However --
Q That's what you've got written up there, I should say?
A Yeah. But this is misleading, so -- it is for surgeons.
Q And, sir, I'm just simply asking you what the words on the paper say.
A Yes.
Q And let's go over to the next page. And

3577

we've got pictures of a number of the meshes that you're looking at. Right?
A Yes.
Q And you got one here that's 2.5. Correct?
A Yes.
Q And where's that PowerPoint?
It looks a whole lot like that Gynemesh PowerPoint?
A Yes.
Q Now, were you testing Gynemesh?
A Gynemesh?
Q Were you testing Gynemesh here?
A Gynemesh?
Q Yes.
A Gynemesh.
Q Or Prolene Soft?
A Yeah. As I said in the deposition, I cannot be sure. There is -- there are a lot of similarities. Whether this was exactly coming out of the product or whether it was specifically done, I cannot state. But it looks quite similar, so from this appearance, there seems not to be a difference.
Q And in this article, you were the author. Correct?
A Yes.

3578

Q And you wrote down 2.5, didn't you?
A Yeah.
Q Jamey, let's go to 104.6. Same article. And let's go down here toward the bottom.
And it says, "Polypropylene has been used in hernia surgery for almost five decades. Compared to other biomaterials, it shows a high biocompatibility, with no degradation but a good integration into the neighboring tissue." Correct?
A Yes.
Q And then, Jamey, let's take that one down.
We'll go to the next one. Sir, this is Defendant's Exhibit DLTB00259.
You're familiar with this one? This is another article that you wrote, sir. Correct?
A Yes.
Q This is in 2001. Correct?
A Yes.
Q And the title of it is "Functional and morphological evaluation of a low-weight, monofilament polypropylene mesh for hernia repair." Correct?
A Yes.
Q And let's go into the abstract, about two or three sentences down, beginning with "In the present study."

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And, sir, in the abstract you often describe what it is you're doing so that the readers don't have to go through the entire article to understand what you're doing. Right?

A Yes.

Q "So in the present study, a low-weight polypropylene mesh (LW)" --

And I assume by that you just mean low weight. Correct?

A Yeah.

Q -- "made purely of monofilaments was compared to a common heavy-weight polypropylene mesh (HW) in regard to the functional consequences and the tissue response."

And then, sir, you go on to indicate that you -- again, you were implanting mesh in rats, and you were letting them go anywhere from three to 90 days, and then you were sacrificing the rats and then you were looking at the mesh after the tissue had grown into it under microscopes and the other instruments that you use. Correct?

A Yeah.

Q And if we go down to the bottom of this page, we actually see right there at the bottom that Ethicon was one of the grant sponsors for this study of

3580

yours. Correct?

A That is correct. They did -- they got a report of it.

Q According to the study, sir, you had -- 90 male rats were studied. Does that sound right?

A Yeah.

Q Let's go to the table on page 131, up toward -- I'm sorry, it's actually 259.3.

Sir, these are the textile characteristics of the two meshes that you were testing. Correct?

A Yes.

Q And you called it here a heavyweight, HW and low weight, low W, and I want to kind of focus in on the LW.

Now, it says 45 grams. Correct?

A Yep.

Q That's basically Gynemesh.

A Yep.

Q Right? It's 45 grams?

A Quite similar, yeah.

Q And the pore sizes here you indicate are greater than 1 millimeter. Correct? Or greater than 1,000 -- well, here you use millimeters. Right?

A Yes.

Q Pore sizes greater than 1 millimeter.

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Correct?

A Yep. That's in the table.

Q And then let's go to the conclusion or toward the end on 259.7.

And, sir, part of what you were looking at here was you were looking at a heavyweight mesh and a lightweight mesh and you were asking yourself or you guys were studying the question whether it's better to have a low weight mesh than a heavyweight mesh in terms of complications. Right?

A Yeah.

Q And when we go here to the end near the bottom where it begins, "Therefore." It's kind of where you're summing up your conclusions. And it says, "Therefore, a reduction of the mesh material, and of the foreign body surface, in particular, to the lowest extent possible is recommended. The present study shows for the first time that this aim can be achieved by the exclusive use of nonabsorbable polypropylene monofilaments."

Did I read that correctly?

A Yes.

Q Sir, I'm handing you Defendant's Exhibit DLTB00150.

Have you seen this before, sir?

3582

A No, I cannot recall it.

Q Sir, the title of this article is "Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery." Correct?

A Yep.

Q All right. And if we look down at the bottom, we see it's published in the Journal of Urology in 2009. Correct?

A Yep.

Q And I don't know if we've covered the Journal of Urology, but that's not a journal that you subscribe to. Correct, sir?

A Not for our department. For the university as well, it is possible, of course.

Q But I don't think -- but you personally don't have a subscription, you don't get this mailed to your home, the journal of urogynecology -- I mean, I'm sorry, the Journal of Urology, do you?

A No, I don't get it at home.

Q And we see that it's authored by -- we've got Carolyn Elmer, Bo Blomgren, Christian Falconer, Anju Zhang and Daniel Altman. Correct?

A Yes.

Q You've got five authors. And it says from

the "Division of Surgery and Urology, Department of Obstetrics and Gynecology, Department of Clinical Sciences" and "Sweden." Correct?
A That is correct.
Q So these are gynecologists who are writing on this issue of inflammatory response to transvaginal polypropylene mesh. Correct?
A Yes, that's correct.
Q And in the purpose it says, "We prospectively evaluated the histological inflammatory response to the large polypropylene transvaginal mesh used for pelvic organ prolapse surgery."
Did I read that right?
A Yes.
Q Then we go down to "Materials and Methods." "Ten patients and 8 controls underwent vaginal punch biopsy sampling before surgery and patients also underwent it one year after pelvic reconstructive surgery using polypropylene mesh. Foreign body response to the mesh was assessed using a combination of histological, semiquantitative and computerized image-based analysis." Correct?
A Yes.
Q And so just to break that down just a little bit, when we talk about ten patients, we're



talking about ten patients who have actually had the polypropylene transvaginal mesh implanted inside their bodies. Correct?
A Yes.
Q And when we talk about eight controls, are we talking about women who have not had the mesh implanted inside their bodies?
A I guess it is just like this, yeah.
Q So when we talk about they underwent vaginal punch biopsy sampling, do you know what that is?
A I don't know exactly how they did it, how deep and --
Q Do you know what it is?
A Yeah. I can imagine.
Q So vaginal punch biopsy sampling is where the doctors actually go into the woman, and they take a biopsy or they pinch out a piece of the woman's own tissue in that area. Correct?
A Yes.
Q And they did it before surgery and then they had it done one year after pelvic reconstructive surgery using the mesh. Correct?
A Yes.
Q So they pulled out some skin -- I'm sorry,



some tissue using the biopsy before they underwent the surgery, and then a year later, another piece of tissue is biopsied out of the same women. Right?
A Yeah.
Q Let's go over to Defendant's Literature 150.2. Let's go up under "Materials and Methods," second sentence. It says, "Ten consecutive patients undergoing pelvic organ prolapse surgery using the Prolift system and eight controls undergoing elective gynecological surgery for other benign indications were included in the study." Right?
A Yes.
Q So these ten women actually had Prolifts in them. Correct?
A Yep.
Q And let's flip over to 150.6. And they tell us here after taking us through all the different mathematical values that they calculate in all their examinations, they tell us that "The combined results of the clinical and histological inflammatory evaluation suggest that biocompatibility was satisfactory."
Did I read that correctly?
A You read this correctly.
Q Jamey, if you could put back up Dr.



Klinge's article, Dr. Muhl and Dr. Klinge's article, DLTB360.
Sir, so we could -- just so I fill the chart out, what did we have for effective porosity over here on Gynemesh/Prolift? 26 percent at rest, 0 percent at strain?
A At strain, 0. And without strain, 26 percent.
Q So we'll go with the lower number.
So we're back here kind of where we started. And, again, sir, I don't want to dwell on the points that we've already discussed with Dr. Muhl, but when you tested the Prolift in 2012, you didn't test the mesh with human tissue incorporated into it. Correct?
A That is correct.
Q Let's go to this article at .7, 360.7.
And just to reorient, the procedure that you outlined in this article is the procedure that you used to test the Prolift and the Gynemesh. Correct?
A Yes.
Q So let's highlight that first sentence there, right above the "Conclusion."
"Though the present technique offers a reproducible way to objectify the porosity of flat textile structures, it is limited to a two-dimensional

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analysis."
Did I read that correctly?
A Yes.
Q And then let's go down to the last sentence in that paragraph, "Furthermore, examination of porosity after tissue incorporation can be measured only if the tissue is completely removed and the textile is kept perfectly flat."
Did I read that correctly?
A Yeah.
Q And now let's go to the first page of the article, point 1 in the abstract, last sentence.
And you told us, sir, when you came up with this protocol in 2007 that "Further in vivo studies" --
And those are studies inside the human body. Right?
A Yes.
Q "Further in vivo studies have to investigate whether the preservation of a high effective porosity under stress may help to improve biocompatibility of textile implants."
Did I read that correctly?
A Yes.
Q And, sir, let's move to 360.3 in the article, toward the bottom under "Porosity

3588

determination."
Sir, you told us there in your article in 2007 that pore sizes that prevent any bridging effect but permit ingrowth of physiological tissue should exceed a distance of 1,000 microns, that's that 1 millimeter we've been talking about, between two polypropylene filaments. Correct?
A Yes.
Q So, sir, you also told us later on in this article, page 360.5, right in the middle, "Pore sizes of greater than 500 to 600 microns permit ingrowth of soft tissue, and pore sizes of greater than 200 to 300 favor neovascularization." Right?
A Yes.
Q The ingrowth of blood vessels. Right?
A Neovascularization is the ingrowth of blood vessels and of soft tissue with scar. Scar and soft tissue as well.
Q When you tested the Prolift in 2012, you tested it at 1,000 microns. Right? In other words, when you tested the effective porosity, you used 1,000 microns?
A 1,000 microns, yes.
Q That's 1 millimeter?
A Yes.

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Q You did not use 500 to 600 microns. Correct? You used 1,000?
A Yes. Because we wanted to have the scar.
Q Now, sir, we're rounding the corner here. I've handed you Defendant's Exhibit DLTB00026.
By the way, sir, when you tested the Prolift in 2012, you tested the Prolift using 1,000 microns, and you tested the DynaMesh at 600 microns. Correct?
A Because it's a PVDF, it's another material.
Q So 1,000 for one and 600 for the other. Right?
A Yeah.
Q Now, sir, I've handed you an article called "Classification of biomaterials and their related complications in abdominal wall hernia surgery."
And let's go up to the very top.
Sir, I think you told us this was the very first edition of Hernia. Right?
A I guess, yeah, it was number one.
Q Yeah, this was number one.
A Yeah.
Q And Hernia is -- I mean, it's a big deal in -- it's a big deal for hernia surgeons. I mean, it's not light reading for the rest of us, but

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hernia surgeons, this is a big article, I mean, it's a big publication, Hernia? Let me phrase -- no, no. Let me phrase it another way.
It's an important journal to hernia surgeons?
A Meanwhile, yeah. They started there.
Q So let's scroll up a little bit.
And this is authored by Prof. Amid. Correct?
A Yes.
Q And you talked about Prof. Amid earlier today. Correct?
A Yes.
Q Let's scroll up just a little bit more.
And what Prof. Amid was concerned with in this article was classifying biomaterials, i.e., meshes among other things, and their related complications in abdominal wall hernia surgery. Correct?
A That is correct.
Q So we see down here for type I, "Type I are totally macroporous prostheses" --
And macroporous, we talked about that earlier, those are the large pore fabrics. Correct?
A You have to decide what is large pore.
Q Let me give it to you a different way.

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Macroporous meshes have larger pores than microporous meshes?
A That is okay.
Q There we go.
Totally macroporous prostheses, and that's prostheses is just another word for --
A Mesh.
Q -- mesh. Right?
A Yes. So we all know.
Q Such as Atrium, Marlex, Prolene and Trelex.
And I think Atrium, Marlex and Prolene were ones you put in some of your patients. Right?
A Yes.
Q "These prostheses contain pores larger than 75 microns." Correct?
A Yes.
Q When we talk about 75 microns, I had to struggle with this, that's why I keep repeating myself, pore sizes that are greater of 1 millimeter, that's 1,000 microns. Right?
A Yes.
Q So when we talk about 75 microns, we're talking about something that's less than 10 percent of that 1 millimeter. Correct? 75 microns --
A Yes.

3592

Q "These prostheses contain pores larger than 750 microns, which is the required pore size for admission of macrophages." Correct?
A Yep.
Q "Fibroblasts"?
A Yep.
Q "Fibroplasia, blood vessels, angiogenesis and collagen fibers into the pores." And then it says, "Bobyn, et al., 1982."
And that would be an article published by Bobyn in 1982. That's what it's talking about there. Right?
A You're right.
Q And then White in 1988. Correct? That's another article?
A Yep.
Q And then White, et al. in 1981. Correct?
A Yes.
Q And then, sir, handing you DLTB00139, "Synthetic and biodegradable prostheses in pelvic floor surgery."
You've seen this article, certainly, sir, haven't you, sir?
A Yes.
Q And this is the Deprest article. Correct?

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Or at least I refer to it as Deprest, because the first author is Deprest. Correct?
A Yes.
Q And as you can see right here, "Center for Surgical Technologies, Faculty of Medicine, Department of Obstetrics and Gynecology" in Belgium. Correct?
A Yes.
Q And so these are pelvic floor surgeons --
A Yes.
Q -- in Belgium discussing synthetic and biodegradable prostheses in pelvic floor surgery. Correct?
A Yes.
Q We've got one, and I think one of them might be a pathologist, but a pathologist is still -- they're still a doctor, aren't they? At least over here in the United States they're a medical doctor. Are pathologists in Belgium also a medical doctor?
A I would guess. I'm not certain, but I guess.
Q We've got one, two, three, four, five, six, seven, eight, nine medical doctors. Correct?
A I cannot control it for everyone, but I guess.
Q And we're talking 2005. Right? That's the year Prolift comes on the market. Right?
A Yes.

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Q And let's go to page 139.4, last sentence. "And these pelvic floor surgeons tell us pore sizes of greater than 75 microns allow for rapid ingrowth of fibroblasts and vascular elements necessary to anchor the implant within the native tissue."
Did I read that correctly?
A You read this correctly.
Q And then, sir, and I promise you we're getting close to the end here, I'm handing you another article. The one I just showed you -- the one up on the board is 2005. Now we're going to 2006, one year later. Jamey, let's put up DLTB00140.
And here we see Deprest again. Correct?
A Yes.
Q And, sir, we see Deprest, Fang Zheng, et cetera. We see -- these are a number of physicians. And I compared -- so Deprest has basically got an article in 2005 and an article in 2006. Correct?
A Yes.
Q And I compared the authors of the two, and there's some overlap, but I think, what did we count, nine on the first one and then I think there are a couple more over here on the 2006 article that are not also co-authors on the 2005 article. I mean, I may have my numbers off, but I think it's somewhere around

11 total medical doctors between the two articles, maybe 12. Okay?

And we see, sir -- Jamey, why don't you take down the one on the left. There you go.

"The biology behind fascial defects and the use of implants in pelvic organ prolapse repair." Correct? Correct, sir?

A Yes.

Q And then let's go to page 140.3. And kind of go toward the bottom. Pick up right there with that sentence beginning with "Pore."

It says, "Pore size is also an important factor for fibroblast infiltration, flexibility and mechanical integration. Pore sizes of greater than 75 microns allow for rapid ingrowth of fibroblasts and vascular elements necessary to anchor the implant within the native tissue."

Did I read that correctly?

A Yes, you read it correct.

Q Sir, Defendant's Exhibit DLTB00261. The title of this article is, "Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes." Correct?

A Yes.

Q And the lead author is Dr. Klinge.



Correct?

A Yes.

Q And it's published -- it was accepted April 2012 and it was published in May of 2012. Correct?

A Yep.

Q Sir, if you would, look with me, page 261.6. That paragraph there, Jamey, that begins "Furthermore," about halfway down.

It says, "However" -- and these are your words. Correct, Dr. Klinge?

A What?

Q These are your words?

A Yeah.

Q "However, it is still open for further studies whether 500 microns is a reliable limit for histology and 1,000 microns for the calculation of the effective porosity or whether this should be modified."

A Yes.

Q Did I read that right?

A Correct.

Q "Though a standardized measurement of the effective porosity that considers only large pores with sufficient geometry to avoid bridging may best provide a qualitative criterion to differentiate these two groups, it may be speculated" --



A Yes.

Q -- "whether the assumption of a best pore size of 1,000 microns for preserving an effective porosity has to be adjusted." Correct?

A That is correct.

MR. GAGE: Nothing further, Your Honor.

- - -

REDIRECT EXAMINATION

- - -

BY MR. ANDERSON:

Q Dr. Klinge, let's actually start right where he ended off.

This 1,000 explant classification, what was the purpose of this being done in Europe for hernia -- for a hernia registry? Explain that hernia registry.

A From the European Hernia Society, we were asked to build up a registry to get better information, what is the outcome of the patients after hernia repair. We all have learned that clinical studies usually have strict limitations, and, therefore, it was -- the task was to build up an international registry. And for this registry, we need some information. We want to put in which material has been used. Meanwhile, more than 220 different mesh materials are used by hernia surgeons. And if you place just a name in this



registry, it will be hardly possible to get any feedback what is the impact of the clinical outcome. And, therefore, we want to have a grouping of these mesh materials so that we can make a better interpretation of these data.

And there, in this field, we categorized two different groups, the so-called small pore meshes and the large pore meshes. And we made it in cooperation with all major manufacturers in Germany, because they wanted to have a classification or a grouping as well.

Q Let me stop you right there.

And one of those manufacturers was Ethicon. Correct?

A Yes.

Q And as part of this regrouping and reclassification of hernia meshes, your work regarding 1,000 microns was listed as one of the ways to classify the meshes that come into this registry in Europe. Correct?

A Yes.

Q And so Ethicon signed off on the registry and the manner in which you set it up for the European Hernia Society. Correct?

A They agreed to this grouping.

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Q Also listed within this article that was just shown to you about the 1,000 explants, this is actually the testing that you and Muhl have done and that the jury has seen. Correct?
A Yes.
Q Showing how you can measure effective porosity by looking at these 1,000-micron pores. Correct?
A Yes.
Q And the importance of having these 1,000-micron pores is also listed in this article, isn't it?
A Yeah. We applied this grouping then to these 1,000 explants. And it is clearly -- can clearly be seen that the mound of inflammation and connective tissue means scar formation is higher in the small pore group meshes than in the large pore group meshes. And, therefore, if we want to have a grouping that predicts a little bit the outcome, we feel comfortable to focus on these pore sizes.
Q And Ethicon is a signatory, they signed off as one of the manufacturers agreeing to this classification and this grouping of meshes in the registry. Correct?
A They agreed to this.

3600

Q Put up Plaintiff's 0689 if you would, please, PLT0689.
MR. GAGE: Your Honor, may we approach?
- - -
(The following occurred at sidebar:)
MR. GAGE: Your Honor, this is a letter to the editor, and --
THE COURT: I usually -- in these cases, I haven't allowed letters to the editor.
MR. ANDERSON: I purposely did not bring up the 1,000 explants because I didn't want to go here. He raised it and he put it up as the last exhibit. And so I wanted to show that their colleagues have thanked them for doing this important work.
MR. GAGE: Your Honor, just for the record, my objection is that it's hearsay because it's a letter to the editor and it's not peer reviewed and it doesn't come within any of the exceptions to the hearsay rule.
MR. ANDERSON: And it's the Hernia journal that he just had this witness say is a very important journal over there. So from the Hernia journal, which he had him establish was so important, here we have commenters, these are authors from the work that he's been showing him for the last two-and-a-half hours, Kockerling and Jacob, and they write in to the Hernia

3601

to say, great job on this reclassification after he's opened the door. Absolutely relevant.
I was going to read the first two paragraphs -- actually, just the first line of the second paragraph. First paragraph and the first line of the second.
MR. GAGE: And, Your Honor, you understand my objection.
THE COURT: The objection is sustained. It's hearsay.
- - -
(The sidebar ended.)
- - -
BY MR. ANDERSON:
Q Just so the jury understands, this 1,000 explant study, how many years of explants -- and by explants, we're talking about tissue that has been taken out of hernia surgery and has been evaluated histopathologically by you and Dr. Klosterhalfen. Correct?
A That's correct. We started to collect these materials soon after 2000.
Q And you published this in 2012. Correct?
A This evaluation of these 1,000. But in between, we have preliminary reports of a group of them.

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Q So 12 years of 1,000 explants that came from human beings that you actually looked at, and you looked at various factors on those. Correct?
A Yes.
Q And pore size was one of them. Correct?
A Pore size was one of it, proliferation and collagen deposition and...
Q And after looking at 1,000 explants, did it confirm your findings that once the fibers in these explants were greater than 1 millimeter but --
MR. GAGE: Objection, leading.
MR. ANDERSON: I'll withdraw it.
BY MR. ANDERSON:
Q Did this paper confirm any of your findings, earlier findings, regarding 1 millimeter is required for fatty tissue ingrowth?
A It is clear that the larger pores are -- have advantages in regards to their partial volume of inflammatory tissue and of connective tissue.
Q So --
A That can be shown by this.
Q So the 1,000 explants, did that confirm or refute your -- did that confirm 1,000 microns was necessary for fatty tissue ingrowth?
A Yeah. Our look at all these explants confirmed

3603

this as a critical cutoff.
Q And was there ever a statement by Prof. Amid in response to this reclassification of hernia meshes?
MR. GAGE: Objection.
THE WITNESS: When he got aware of this, he sent an e-mail with a congratulations.
MR. GAGE: Objection, Your Honor.
THE COURT: The objection is sustained as to what Dr. Amid's response was. It was a hearsay e-mail as opposed to something the doctor published.
MR. ANDERSON: That's fine.
BY MR. ANDERSON:
Q You were just shown an article by Jan Deprest. And what was read to you is, "Pore size is also an important factor for fibroblast infiltration, flexibility and mechanical integration."
Now, I want to clear this up, because there was 75 microns, 1,000 microns and 1 millimeter. And I want to clear this up for the jury, if we could, please.
What happens --
MR. ANDERSON: Do you mind if I use your paper?
MR. GAGE: No.

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MR. ANDERSON: Thank you.
BY MR. ANDERSON:
Q What happens -- what types of cells can go into a small pore that has 75 microns?
A So most of the local cells, inflammatory cells, are in a range of 5 to 7 microns. So you can choose whether -- yeah. 5 -- 15 of these cells can go parallel into these microns.
Q So if the mesh has holes that are only 75 microns, can any new tissue ingrowth occur?
A It depends what is the definition of a tissue.
Q Thank you.
What type of tissue can grow in at 75 microns?
A You always will find that there are some macrophages in combination with some fibroblasts. No one will object to this.
Q Fibroblasts meaning scarring?
A Scarring.
Q So at 75 microns in the pore, we still have scar. Correct?
A Yes.
Q Then the next thing he read to you was, "Peak ingrowth is reached at pore size around 400 to 500 microns." Correct?

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A Yeah.
Q What can grow into the pore at 400 to 500 microns? What type of cells, if that is laying in a human tissue, and these are the size of the mesh hole?
A This limit usually is taken -- if you have some tissue ingrowth, you need some vessels for providing the blood supply in it. And it was generally accepted that you need a pore size of this diameter so that pore -- that vessels are growing in and providing these cells with blood. If the pores are smaller, you don't have this ingrowth of the vessels. So this is a cutoff for -- that you see ingrowth of vessels.
Q So you can get some vessels?
A Yes.
Q Will you get new fatty tissue ingrowth that we want for the implant to remain flexible?
A No. We didn't see it -- we didn't saw it in these small pores.
Q And you called fat tissue good tissue. Correct?
A Fat tissue is good tissue, because it means that it is -- yeah. It is not replaced by scar tissue.
Q So at 75 microns, you can get a few macrophages, and that's just our body's white blood

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cells, to eat some tiny bacteria. Correct?
A Macrophages, few fibroblasts, so -- but there is only room for 10, 15 cells in a row.
Q Correct. So when the hole gets bigger to 400 to 500 microns, you can get some vessels, but no fat. I don't write as good as Will.
No fat, still no good tissue. Correct?
A We don't see any fat there.
Q Then what wasn't read to you from this article, I would like to, which says, after the sentence, "Peak ingrowth is reached at pore size around 400 to 500 microns."
And that would be ingrowth of scar tissue. Correct? Ingrowth of scar tissue?
A Yep.
Q Right. So when they're talking tissue ingrowth, they're not talking good tissue ingrowth, they're talking bad tissue ingrowth. Correct?
A They don't differentiate it.
Q Right. So then larger pores -- after that it says, "Larger pores limit the fibrosis process to the perifilament region."
That was those pictures we saw with the little dots around the side. Correct?
A That is --

Q And if they were far enough away, we would have a good fat in it, but if we had these three together, like we saw in multiple things, it would get a scar plate. Correct?
A So they are absolutely in line with our conception.
Q So when it says, "Larger pores limit the fibrosis process to the perifilament region, the pores get filled with fat."
Did you see that in the article?
A Yeah. I --
Q The reference is number 38. That was not read to you either from this Jan Deprest article.
Let's look and see what reference 38 is regarding larger pores.
A I'm lost.
Q I've got you. I'll show it to you.
MR. ANDERSON: May I approach, Your Honor?
THE COURT: Uh-huh.
BY MR. ANDERSON:
Q Do you see 38?
A Klinge, Klosterhalfen, Birkenhauer. It's our publication in 2002.
Q Is that one of the articles that we went through with the jury at the earlier part of this day?



A Exactly.
Q And is that the one where you first reported that in order to get large porous -- in order to get fat tissue, good tissue to grow in, that you needed --
A Yes.
Q -- greater than 1 millimeter?
A Yes.
Q So it's not until you get to 1,000 microns; is this correct, sir?
A Yes.
Q It's not till you get to 1,000 microns, Dr. Klinge, that you actually get good tissue. Correct?
A Exactly.
Q He was showing you that Amid classification. If we took and went off the chart this way, that's where Dr. Amid's classification would be. Correct?
A Yes.
Q And that was before there were lighter weight, larger pore meshes. Correct?
A At that time, there haven't been any.
Q His classification was only for heavyweight, small pore meshes. Correct?
A Yes.



Q Because they didn't have lightweight, large pore meshes at the time, did they?
A No, they didn't.
Q Not until the next year when you came out with the lightweight, large pore concept that they helped you develop. Correct?
MR. GAGE: Objection, leading.
THE WITNESS: That is correct.
THE COURT: The objection is overruled.
THE WITNESS: In December I talked to --
BY MR. ANDERSON:
Q No question pending. It's okay.
Did you want to say something about that?
A No.
Q Okay. Defense counsel also showed you the Muhl article, and he read you some very similar things. He said, "Pore sizes of 500 to 600 microns permit ingrowth of soft tissue."
And then he said, you didn't test -- you didn't test the Prolift at 1,000 -- at 500 to 600, you tested it at 1,000.
Do you remember that part of your testimony?
A Yes, yes.
Q Why did you test it at 1,000 and not 500 to



600?
A We wanted to identify the area where we don't have this scar, because in some patients, the scar is a problem, and, therefore, we want to identify what is a risk of a device to initiate scar tissue. And therefore, we took the cutoff of 1,000.
Q And that's for polypropylene. Correct?
A That's for polypropylene.
Q And then he pointed out that you used a different standard for the DynaMesh?
A Yes.
Q Why did you use a different one for DynaMesh?
A We -- it was another polymer. We started to work on it in 1998.
Q What's that made out of?
A It's polyvinylidene fluoride.
Q Called PVDF?
A PVDF. It has two fluorine atoms added a little bit more hydroflow but is said to be more stable. And in our first experience, we saw that the foreign body reaction, this infiltrate and the fibrosis, that this area is smaller with the PVDF than with the polypropylene.
Q So in other words, the tissue, you have a

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greater inflammatory response to polypropylene meshes than you do to PVDF meshes. Correct?
A In comparison to PVDF. And, therefore, for the PVDF, the pores can be smaller to prevent this scarring integration.
Q The jury has heard a little bit about Project Thunder. Project Thunder was the project that Ethicon was looking at as one of the alternatives to replace Gynemesh PS. Do you recall that?
A Yes, yes.
Q Project Lightning was something they were looking at to replace Gynemesh PS, and that was Prolift+M. Is that your understanding?
A Yes.
Q And then they were also looking at Project Thunder. Correct?
A Yes.
Q The material they were looking at in Project Thunder was PVDF, wasn't it?
A Yes, yes, exactly.
Q You helped do some of those studies. Correct?
A Yes.
Q In fact, who provided you the PVDF samples when you did your first comparison to PVDF versus

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polypropylene?
A The first PVDF mesh came from Ethicon.
Q Before I go into the Thunder document, you, in that 1,000 explant article that we were looking at, it said that the 1,000 microns could be speculative. You didn't get a chance to explain that. Please explain that to the jury.
A We made -- or there is some data that 1,000 microns are the cutoff, but it is possible that if you have additional surgical trauma to this, that this limit of 1,000 is maybe not the best to differentiate good meshes from the bad meshes. And, therefore, we offer or we said in this manuscript that you have to study it further on. We made -- we have some evidence that the cutoff is about 1,000, but there may be some other conditions where this may be modified. But this has to be done, and we offer -- and, therefore, we published it because we offered this as a technology for everyone, for every manufacturer to work on this.
Q Thank you for explaining that.
Can we go to Plaintiff's 1664?
We were talking about Project Thunder and Project Lightning. Correct?
A Yes.

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Q Could you please go back to Plaintiff's -- the slide 50 on that, please, the very last one.
Look at the top there. "Lightning." They said that they could "maybe have that in 12 months or less. It's a quick hit, modification to our existing product, likely naked Ultrapro."
That would be once the Monocryl sutures absorbed and it would actually have large pores. Correct?
A That is simply taking a hernia mesh and placing it again in the pelvic floor.
Q But the Ultrapro pores were 4 to 5 millimeters. Correct?
A Yes. Rather large pores.
Q They didn't have those bars running through them, did they?
A No, they didn't.
Q And it was almost half the weight of Gynemesh PS. Correct?
A Yes, yes.
Q So if you're looking for a lighter weight, larger pore mesh than Gynemesh PS, they had it?
A They had it. And Ultrapro is the most often used mesh for hernia surgery.
Q And if you go to the final -- keep that up.

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Take the bottom bullet point, please.
But Project Thunder was going to take a little longer. "The holy grail of pelvic floor repair meshes, a new weave, matched to the tissue properties of native tissue."
Do you see that?
A Yes.
Q And we saw the slide earlier that said there was no patient-centric graft material?
A Yes.
Q And that's why they were looking at this?
A Yes, exactly.
Q Is this what you were telling the jury earlier about that you need to look at the physiological requirements of the area of the body where you're going to place mesh?
A Yeah. This is in line with this. But it obviously takes three years or four years to develop this.
Q And how long did it take to develop, for instance, Vypro hernia?
A Vypro was ready within three years.
Q And Ultrapro was how long?
A It was about five years.
Q So if this was going to be the holy grail

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of pelvic floor repair mesh materials and they knew they had a problem with Gynemesh PS, does this apply to what you said earlier, stop and study?
A Yeah. It's a good -- perfect option.
Q And this was going to be made out of the PVDF that had less inflammatory response according to your studies?
A This is completely in line with what we said.
Q But did you see the documents in Ethicon's documents where they said that they killed Project Thunder? Correct?
A Yes.
Q You were asked some questions about Prof. Muhl's testing with the DynaMesh versus the Gynemesh PS. Correct?
A Yes.
Q That we did for this litigation and for the jury?
A Yes.
Q When you put 3 pounds of force or placed on the Gynemesh PS, did it curl and rope and bend?
A Yes.
Q No. On the -- I'm sorry. On the Gynemesh.
A On the Gynemesh, yes.
Q On the Gynemesh, we saw how when you put 1

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to 3 pounds of force, that it pulled it and there were pore deformation. Correct?
A Yes.
Q Did that happen to the DynaMesh that's made out of PVDF?
A No, it did not, but it was intended not to do this, so it --
Q Do you mean DynaMesh was made not to do this?
A Yes. It was the purpose not to show this collapse of pores when there is some strain to it.
Q So you -- and DynaMesh has arms like Gynemesh. Correct?
A No. The arms were specifically or were made in a standard way. In the Gynemesh, the arms, it was just cut off a huge piece of a larger mesh. And if you are looking to the arms, they are looking quite different at every centimeter. So it will be hardly possible to define any property of these arms, because sometimes the filaments are running like this, sometimes like this. So always different flexibility, stretchability, so -- and in the DynaMesh, it is made very strict and very standardized. But it was by intention again.
Q So DynaMesh, PVDF, did you see in the Ethicon documents where they indicated what they wanted

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was a scar net, not a scar plate, that was the design intent of Gynemesh PS?
A Yes, yes, yes.
Q From your review and all of the work that you've done, were they able to achieve just a scar net, or does Gynemesh PS turn into a scar plate?
A No, they were not able to produce this. And I never, ever -- well, I not ever saw the data that they tried it, to make these modifications. What happens if the pore size is increased by 30 percent? If there -- one of these crossing bars is removed, what happens? All these data, I didn't find it.
Q For the DynaMesh made out of PVDF, is this the construction, regular-sized pores in squares?
A Roughly, but --
Q And when you put 3 pounds of weight, it doesn't lose its structure, did it, in your testing?
A Yes. It is intended to have this high structural stability, because it is intended to be placed in an area where a mechanical strain is applied.
Q But the Gynemesh PS has bars running all through it here, here, here, here. Correct?
A Yes.
Q It has four bars running through each pore. Correct?

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A Yes.
Q And when it's put to the test on 3 pounds, what happens to it?
A Yeah. The pores collapse. But, therefore, we have a big institute for textile engineering because it's a science. There are people who are studying it, not the surgeons. So I have to admit, there is my limit. I just have to go to them and ask them how to realize what is necessary.
Q You were shown some results from a polypropylene study that you did. And although the pore design was not named, defense counsel said, well, isn't this -- doesn't this look like --
MR. ANDERSON: I can approach, please, Your Honor?
THE COURT: You can.
BY MR. ANDERSON:
Q Doesn't this look like Gynemesh PS? In fact, it's only got one bar running through the middle of the pore, doesn't it?
A Therefore, it is similar, but I'm not sure.
Q It's not the same, it doesn't have four bars running through it, does it?
A Yes, you're right. You're right.
Q You told the jury before if it has four

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bars running through it, it brings the inflammation into the pores. Correct?
A Yes.
Q It will have a greater inflammatory response?
A Yes.
Q Fibrotic bridging?
A Yes.
Q Scar plates?
A Yes.
Q Shrinkage?
A Of course.
Q Patient complications?
A Yes.
Q This here, it's dense. This was shown to you and put on the screen. Do you remember that?
A Yes.
Q And they drew a line over here and said, well, this is 2.5 millimeters and this is 1.75 millimeters. So we've got a big pore. Do you remember that?
A Yes.
Q In that big pore, they have all kinds of fibers and lines running through it that you told the jury before would bring fibrosis into that pore.

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Correct?
A Yeah.
Q Did you read the testimony of Dan Burkley, the porosity tester for Ethicon?
A We have shown it.
Q And you've read his deposition. Correct?
A Yep.
Q Do you recall he said he has no idea where those numbers came from that you see here?
MR. GAGE: Objection, Your Honor.
THE WITNESS: Yes.
THE COURT: The objection is sustained. The jury should disregard the last answer unless you intend to play it for the jury.
BY MR. ANDERSON:
Q You were shown this by defense counsel, one of the many hernia articles that he showed you.
Let me ask you this. Any of your hernia articles and any of the ones he showed you, in any of them did you say that Gynemesh PS would be safe in a woman's pelvis?
A No.
Q Most all these articles are hernia. Correct?
A Yes.

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Q And in this study he showed you some titanium polypropylene, about biocompatibility. Correct?
A Yes.
Q One thing that wasn't read to you, "However, there are no data available analyzing the pure effect of titanium coating on biocompatibility in the in vivo situation." Correct?
A Yes.
Q So they don't know what it's going to do in a human being. Correct?
A No. It's one of the studies to investigate, to study it.
Q You were also shown a PTFE study comparing Optilene LP. Do you remember that?
A Yes.
Q What's a better indicator as to whether or not a mesh is going to be safely implanted in a woman's pelvic tissue the rest of her life? Clinical results or what it looks like in a pig after three months?
A The most important aspect whether a mesh is a good mesh or a bad mesh, of course, are the clinical results. But to predict this in the -- if you want to make a development of the best meshes, we have to go to preclinical tests. And these will help us to find the

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best solution, but the most important thing is whether it really works or not. So if you have good experiments and it doesn't work because you have some patients with complaints, it will not help.
And, therefore, the most critical question is if there is someone coming with shrinkage and contraction, regardless how often it is, could it have been avoided, yes or not? Did we do all our best to avoid these problems with the scar is sufficient studying of this phenomenon. And this is the most important thing. And all the other things are attempted just to help.
Q You had some questions about this Jan Deprest article, about synthetic implants and that these knitted structures showed various degrees of inflammatory response.
Do you remember seeing this article?
A Yes, I've seen that. I mean, some way, yeah.
Q I want to read to you what defense counsel didn't read.
"These foreign materials induce first an acute inflammatory reaction which in the case of permanent materials transits to a chronic inflammatory reaction and fibrosis."
Do you agree with that?

A Yes, totally. I met Jan Deprest in December in Cologne, and he -- there is no conflict in our opinions about this cutoff. And he's going to switch to PVDF.

Q The cutoff, you mean 1 millimeter?

A Yes. So large pore is accepted by him as well.

Q And you were shown your lightweight, large pore concept article. Correct?

A Yes.

Q This sentence was read to you.

"Bridging occurs in all mesh modifications with a granuloma size around each fiber exceeding more than half the pore size," and then defense counsel stopped. The next sentence says, "Usually the phenomenon of bridging is observed in all mesh modifications with a pore size of less than 1 millimeter."

Further confirmation of what we've been telling the jury here today?

A Yes.

Q Defense counsel showed you this e-mail from Michel Cosson to this Josh Samon. And he read to you, "Is it critical that mesh straps lay flat in the channel or is it okay to be rolled up?" And then he says, "Cosson," Dr. Cosson says, "if the mesh is in place, there is no problem for a roll-up."



Do you remember that?

A Yes.

Q And you said something at the end of that about class level 5?

A Yes.

Q Can you explain to the jury what you were trying to talk about right there?

A So we have certain degrees of the way we classify the evidence, what is the highest evidence, what gives us the best security that it is reliable advice. So there is a grading of the evidence from 1 to 5. And 5 is the expert opinion. So if someone is standing up and said, okay, it's like this, without showing any data or any studies and so on, and this is, of course, the lowest level of evidence. So if you --

Q Opinion versus data, is that what you're saying?

A Yes, yes, exactly.

Q Did you see any data --

A No.

Q -- after this where Ethicon actually looked at data, meaning performed studies, so that they could look at what would happen with this rolling up while going through a woman's groin and through her buttocks? Did you ever see any of that?



A No, I didn't see any data or any studies where this was in the focus of the project.

Q So Michel Cosson, he believes that the mesh in place is no problem for a roll-up.

Of course, he doesn't have the arms going through his groin, does he?

MR. GAGE: Objection.

THE COURT: That is argumentative and that question is stricken. The jury should disregard it.

BY MR. ANDERSON:

Q The point is that Ethicon did get e-mails, as we saw earlier from Dr. Eberhard, where she indicated that the patients were feeling it in their tissue. Correct?

A Yes. And this is the classical situation where you have conflicting results, and then you have to study it. Otherwise, I don't know how you can get a good solution.

Q You were shown an article about pelvic organ prolapse, Prolift system that was in 75 patients. Do you recall that?

A Yes.

Q What will this data tell you from 75 patients?

A So there are a lot of data with patients, 15, 20



patients, 100 patients. And all these clinical trials help to find out whether there are some complications, but they usually have not sufficient statistical power to say any more, to say what is the safety of these -- of this device. And, therefore, the value of these clinical trials is too low to say, okay, you made an evaluation and that is reality.

Q And what wasn't read to you, I want to read to you now and see if you agree.

"Numerous studies have reported on short-term outcomes" --

MR. GAGE: Objection, Your Honor, I was not allowed to go into this.

MR. ANDERSON: Certainly was.

THE COURT: Well, let's approach.

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(The following occurred at sidebar:)

MR. ANDERSON: I showed the other thing that he went into. He showed Milani, he showed the cover of it, he read the abstract. And then he went to the numbers. And after he had gone through the numbers for a long time, we finally said, Your Honor, he's getting too deep into the numbers and so he was able to say Ultrapro was bigger than the other. But he was allowed to read this entire thing, but he chose not to

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read that.
THE COURT: Okay. I'll allow you to use just the first sentence it says long-term studies -- it doesn't appear to be too detailed, but it's appropriate.
MR. ANDERSON: Thank you.
- - -
(The sidebar ended.)
- - -
BY MR. ANDERSON:
Q The sentence that wasn't read to you is, "Numerous studies have reported on short-term outcomes of this procedure but long-term studies are lacking."
Do you agree that long-term studies were lacking on Prolift --
A Definitely.
Q -- when it went to market on March 2005?
A This sentence can be found in many other articles as well.
Q Here's another one that he showed you about tension-free vaginal mesh. What wasn't read to you is, "A long-term study on a large number of patients is still warranted to confirm and validate the clinical use."
Would have been a good idea, wouldn't it?

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MR. GAGE: Objection, argumentative.
MR. ANDERSON: Withdrawn.
THE COURT: The objection is sustained. The jury should disregard it.
BY MR. ANDERSON:
Q Defense counsel spent about the first 40 minutes talking about hernias. So I want to talk a little bit about that with you.
If millions of people have polypropylene in one part of their body, does that mean that that polypropylene is going to be safe in another part of the body?
A No. You can transfer this -- in this general -- it is not adequate to say this.
Q If a surgical mesh for polypropylene may be okay in one kind of hernia, does that mean it will be okay to wrap it around another organ like your eye, like your heart, like your lungs?
A No, definitely not.
Q Like a woman's pelvic tissue?
MR. GAGE: Objection, Your Honor.
THE WITNESS: Therefore, the abdominal wall situation --
THE COURT: The objection is overruled. He can answer.

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BY MR. ANDERSON:
Q Go ahead.
A Yeah. The abdominal wall is a completely different setting. The mesh is placed at a different place. And it is more easy to remove the mesh if you have some failures.
Q Can you put up that slide, please?
I want to go back, if I could -- no. The one before, please.
Do you remember when we were looking at the Ethicon minutes from that 2007 Norderstedt expert meeting?
MR. GAGE: Your Honor, objection. Beyond the scope of my cross.
MR. ANDERSON: It's hernia surgery, Your Honor.
THE COURT: I'll allow it.
BY MR. ANDERSON:
Q What Kirsten Spychaj said at that meeting was, "In pelvic floor surgery, shrinkage seems to be more important than in hernia surgery."
Did you read that?
A Yes, I read that.
Q Did you agree with that as a hernia surgeon?

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A Yes. I agree to this, yeah.
Q In other words, when you have contracted mesh in the hernia or in the abdomen, it's a lot different than having contracted mesh in a woman's pelvic tissue. Correct?
A Yes, definitely.
Q And in and around her pelvic organs?
A Yes. The latter, it will be impossible to remove these.
Q Let's talk about some of the difference between abdominal mesh repair and pelvic floor mesh repair, since it was brought up by defense counsel.
Abdominal mesh repair, it's a flat mesh. Correct?
A It's a completely flat -- or it's a flat, two-dimensional mesh. It doesn't have this three-dimensional configuration. It is usually placed without any tension. It is very often laying only in fatty tissue. It's much easier to remove in the abdominal wall. There are areas where it's difficult to remove, and there, we are very limited or we don't like it to place there a mesh, only in some desperate cases we would do so.
Q Let me stop you right there.
MR. GAGE: Your Honor, I object. Pelvic

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floor mesh repair is clearly not his area of specialty. He shouldn't even talk about -- what's on the left, that's what I covered with him, but on the right, he shouldn't because he's not qualified.

MR. ANDERSON: He's been asked article after article about meshes in pelvic floor repair.

MR. GAGE: But not like that, Your Honor. Not going through that sort of stuff. And he's trying to convert over into a pelvic surgeon, which he's clearly not.

MR. ANDERSON: I absolutely disagree.

THE COURT: I think he's still talking about the quality of the material itself and how the material is used. Therefore, I'm going to allow it.

MR. ANDERSON: Thank you, Your Honor.

BY MR. ANDERSON:

Q So let's look at the first one. A flat mesh laying in the abdomen, like defense counsel pointed out earlier. Correct?

A Yes.

Q Whereas when you talk about a three-dimensional mesh, do you mean going in and around the pelvic organs, out through the woman's groin and down through her buttocks?

A Yes.

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Q And when you say without tension, you can lay that abdominal mesh flat like this. Correct?

A Yeah. It's flat. We don't even use any fixation. It is just placed between the tissue, and usually it stays there. There are no arms or something putting on some mechanical strain.

Q And you said this is laying in fatty tissue versus the female organs where there's a lot of nerves. So instead of laying here, it's going all through here where there's lots of different nerve endings, nerve channels and nerve branches. Correct?

A Yes. We are happy as an abdominal wall surgeon that we can place the mesh in this layer of fat tissue where there are little nerves and where the reaction is quite smooth.

Q I think one of the big points you just raised a minute ago that I want to go to is, it's easier to remove this flat mesh in the abdomen and almost impossible to remove the mesh from a woman's vagina and in and around her pelvic organs.

Is that your understanding as a hernia surgeon, that it's easier to remove here?

MR. GAGE: Objection, qualifications. He's deep into pelvic floor surgery.

THE COURT: Doctor, do you have the

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experience or expertise to discuss whether it's difficult to remove mesh from the pelvic area?

THE WITNESS: I know from all documents where the specialists in the pelvic floor surgery said that it is almost impossible to remove it. I know from the abdominal wall that --

THE COURT: I'll allow you to give your opinion based on your review of the materials.

MR. ANDERSON: Thank you. I was actually just moving to the last bullet point.

BY MR. ANDERSON:

Q You talked about in hernia, with repairing an abdominal hernia mesh, if you have a hernia that's like this, you actually, if the place that you want to repair is here, you said you have to have 5 centimeters extra around the edges of the area that you want to repair; is that correct?

A That is correct. That is a principle.

Q And why do hernia surgeons have to do that with polypropylene meshes?

A Because we know that there will be considerable shrinkage, that this mesh will become smaller. And if it's too small, then you will have a recurrence and another hernia. And, therefore, we want to make this wide overlap. And if you place it in the abdominal

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wall, there is much space to do so.

Q The Gynemesh PS is precut. Correct?

A Yes.

Q Is there any way to allow for the shrinkage if it's precut? If it's already cut in this fashion, there's no way to allow for the shrinkage in order to make sure it covers the organs, is there?

A I have no idea how this may work.

Q You said earlier that there are certain types of hernia repair where you absolutely would not use polypropylene mesh. Correct?

A Not absolutely, but very restrictive in our limitations.

Q And one of those is around the esophagus where you have a hiatal hernia. Correct?

A Yes, yes, yes. We know that when we place a mesh, the recurrence rate is lower. We know this, but there are some patients where it may come that the mesh migrates into the esophagus and cut off -- yeah, migrates into -- made an erosion into the esophagus. And the reoperation is a big challenge, and -- sometimes with mortality, and, therefore, it is a common agreement among abdominal surgeons not to use it as a first choice, but only in patients where it -- we don't know what to do else, then we use the mesh.

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Q Can you put the last slide up, please?
Have you seen this slide by the worldwide medical affairs director, David Robinson at Ethicon, "The vagina is not the abdomen nor similar to any other surgical environment"? Do you agree with that, sir?
A Yes.
MR. GAGE: Same objection, Your Honor, as to the timing after date of surgery, I believe.
MR. ANDERSON: No. It predates it. This is when Dr. Robinson --
THE COURT: It does predate it? The objection is overruled.
MR. ANDERSON: Yes, ma'am.
BY MR. ANDERSON:
Q Do you agree with that?
A Yes.
THE COURT: Counsel, if you only have a few more minutes, otherwise we're going to have to bring the jury back tomorrow and --
MR. ANDERSON: Last question. Last question.
BY MR. ANDERSON:
Q Do you agree with that statement?
A Yes.
MR. ANDERSON: No further questions.

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RECROSS-EXAMINATION
- - -
BY MR. GAGE:
Q Sir, you talked about a spreadsheet of over 1,000 implants. As far as you know, not a single one of them was Prolift or Gynemesh. Correct?
A Yes.
Q Dr. Cosson's e-mail, he's a urogynecologist, he's a surgeon, he implants Prolifts and you do not. Correct?
A Yes.
Q PVDF mesh, you've constructed a mesh in the pelvic floor made out of PVDF. For pelvic floor repair, there are no studies that you're aware of that demonstrate that PVDF mesh is superior to polypropylene mesh. Correct?
A Yes.
Q And, sir, you were shown this. Do you remember?
A Yes.
Q Talked about the bar going down the middle?
A Yeah.
Q You said that can't be 2.5 millimeter, that's the wrong way to measure it. Right?

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A Yes.
Q This is your article, we showed it, jury saw it, 2004, it's got your name on it. Correct? That's one of the ones we went through earlier?
A Yes.
Q There's the picture, mesh with a bar going down the middle of it?
A Yes.
Q And the numbers 2.5 appear there.
And, sir, my question to you is, you were the author of the article. Who put the 2.5 in your article?
A Is the question to me?
Q Yes.
A Sorry.
Q You're the author of the article. It's got --
A I'm a co-author --
Q It's got 2.5 in your article. Correct?
A Yes. It is an article for surgeons.
Q You were asked a question that -- about TiMesh.
You were shown one of the dog studies and they said, this is a dog study, it's not a human study. Right? Do you remember that just a second ago, Mr.

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Anderson?
A No, I don't.
THE COURT: I think he said it wasn't a pig study.
MR. GAGE: It wasn't a pig study.
THE COURT: I think he asked him about a pig study, but go ahead.
BY MR. GAGE:
Q He said it was a pig study.
In fact, sir, I actually showed you a TiMesh article that was a randomized, controlled, single-center clinical trial involving 102 patients, didn't I?
A Yeah. I had several discussions with Prof. Klosterhalfen about the value of this study.
Q And that article found that TiMesh, and we read the conclusion, it was a light titanium covered polypropylene mesh, it was associated with less postoperative pain in the short term, lower analgesic consumption and a quicker return to everyday activities. Do you remember we went through that?
A TiMesh is specifically designed for the hernia, and it is not a very bad mesh.
Q And so Optilene, 0 percent effective porosity, good integration, no bridging scar tissue,

good biocompatibility.
We pulled those quotes out of articles. Correct? That's my question to you. We pulled those quotes out of articles that we showed the jury. Correct?
A Yeah, yeah. You took it out.
Q And TiMesh, 0 percent effective porosity, good biocompatibility, less postoperative pain, quicker return to everyday activities and best biocompatibility.
In fact, we pulled those out of articles. Correct?
A Both in a specific setting of experiments.
Q And then here we had Gynemesh and Prolift and you said with strain, it's got 0 percent effective porosity, and then I showed you a biopsy article of women who had Prolift meshes that you had never seen before, and biocompatibility was satisfactory according to those pelvic surgeons. Correct?
A If you look --
Q Is my question true, yes or no? That's what the authors concluded, biocompatibility was satisfactory, yes or no?
A That is not justified, because they only have a very small --



MR. GAGE: Your Honor, it's a yes or no question.
THE COURT: The question is just is that what the authors -- did that language come from that article?
THE WITNESS: If you read it completely, yes.
MR. GAGE: Your Honor --
BY MR. GAGE:
Q My question was yes or no, those words appear in that article?
A Yes.
MR. GAGE: Nothing further.
- - -
REDIRECT EXAMINATION
- - -
BY MR. ANDERSON:
Q What were you trying to explain right there he wasn't allowing you?
A If you look to "Material and Methods" there, they are looking to an area of 58 square microns. That is a very, very tiny area. So you need more patients. The power of this study is very, very low, and you have to look to a wider area of tissue, not only these 60 square millimeters. That's within the inflammatory



infiltrate. So what to learn from this? I don't know it.
Q Counsel just pointed out, he showed you your article and said you were the author of this, sir, 2.5 millimeters. You were the author in 2004. Do you remember that?
A The point was --
Q Do you remember that question?
A Yes.
Q That was before you had a chance to look at 15,000 pages of internal Ethicon documents and determine that 2.5 is wrong; isn't that correct?
A That is correct.
MR. GAGE: Objection, Your Honor.
THE COURT: That is leading.
MR. ANDERSON: No further questions.
THE COURT: Objection sustained. The question and answer are stricken.
Okay. The jury can go out and if the jury has any -- unless, Mr. Gage, did you have anything else?
MR. GAGE: No, Your Honor.
THE COURT: Then the jury can go out, we'll see if they have any questions.
- - -



(The jury leaves the courtroom.)
- - -
THE CLERK: No questions.
THE COURT: 9:30 tomorrow.
- - -
(Witness excused.)
- - -
(Adjourned at approximately 5:01 p.m.)

C E R T I F I C A T I O N

I, ANN MARIE MITCHELL, CCR, RDR, CRR, Realtime Systems Administrator, License Number 30XI00212000, a Certified Court Reporter in and for the State of New Jersey, do hereby certify the foregoing to be prepared in full compliance with the current Transcript Format for Judicial Proceedings and is a true and accurate compressed transcript to the best of my knowledge and ability.

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ANN MARIE MITCHELL, CCR-RDR-CRR
NJ Certified Court Reporter